



HANDBOOK FOR GRANTS ASSISTANTS

Prepared by:
REFERRAL AND REVIEW BRANCH
DIVISION OF RESEARCH GRANTS
DECEMBER 1987

PHONE NUMBERS FOR YOUR INFORMATION

| <u>Office</u> | <u>Key Person</u> | <u>Telephone #</u> |
|---|-------------------|--------------------|
| Barwood Taxi Club Service (24 hour service) | | 652-8500 |
| Cafeteria (Westwood Bldg.) | Bruce Carter | 496-7520 |
| Committee Management Office | Mary Shook | 496-7534 |
| Credit Union (Bldg. 31) | | 496-4758 |
| Emergency - Fire, First Aid, Ambulance | | 116 |
| Fire Wardens - Building Warden | John Wassell | 496-7881 |
| Deputy Warden | Dave Dwyer | 496-7881 |
| Assistant Warden | Barbara Wassell | 496-7337 |
| FTS Problems (identify trouble as FTS) | | 496-5671 |
| Human Subjects Office | | 496-7041 |
| Long Distance Calls - 8 + area code + telephone # | | |
| Long Distance Information | area code + | 555-1212 |
| Mail Room (Main) | | 496-5651 |
| Mail Room (Westwood) | | 496-7236 |
| NIH Telephone Information | | 496-2351 |
| NIH Mugs | Lola Beye | 365-8908 |
| Nurse's Office (Westwood Bldg.) | | 496-7638 |
| OBER Travel (NIH Reservation) - Reservations & Tickets | | 496-8900 |
| Office Services | | 496-9797 |
| Parking Office | | 496-6851 |
| Personnel (DRG) | | 496-7577 |
| Police | | 115 |
| Print Shop (Westwood Bldg.) | Mr. Tyler | 496-0125 |
| Referral Office | | 496-7447 |
| R & W (Westwood Bldg.) | | 496-7540 |
| Security Guard (Westwood Bldg.) | | 496-7250 |
| Supervisor on Duty (before 8:30 am) | Dr. Kraner | 496-7771 |
| (after 5:00 pm) | Dr. Remondini | 496-7271 |
| Supply Store (Westwood Bldg.) | | 496-7580 |
| TIME | | 844-2525 |
| Transportation | | 496-4380 |
| Travel (DRG): Consultants & Govt. Employees | Joe McPherson | 496-6604 |
| User Resource Office | Nancy Curling | 496-1061 |
| WEATHER | | 936-1212 |
| Xerox Room (2nd Floor Westwood Bldg.) | James Webb | 496-7010 |

TO PLACE 800 CALL, DIAL 119 PLUS 800 AND THE SEVEN DIGIT NUMBER

NOTES: _____

P R E F A C E

This Handbook is a training and reference manual for Grants Assistants and Grants Clerks in the Review Sections of the Referral and Review Branch of the Division of Research Grants of the National Institutes of Health. It includes both a general discussion of the office procedures and also a description of the various steps involved in receiving, processing, and reviewing grant applications. Since the Handbook will be continually revised and updated, the material is arranged in such a way as to make updating easier. Your assistance in the revising of the Handbook would be appreciated. Please forward any suggestions to the Office of the Chief, Referral and Review Branch, Division of Research Grants, Room 338, Westwood Building.

CONTENTS

| CHAPTER | | PAGE |
|---------|--|------|
| I. | <u>Introduction</u> | |
| | A. The National Institutes of Health | 1 |
| | B. Extramural Funding | 2 |
| | C. How a Research Grant is Awarded | 2 |
| | D. The Division of Research Grants | 3 |
| II. | <u>Study Sections</u> | |
| | A. Study Section Office | 11 |
| | B. Study Section Membership | 11 |
| | C. Types of Study Sections | 11 |
| | 1. Chartered Study Sections..... | 11 |
| | 2. Ad Hoc Study Sections..... | 12 |
| | D. Procedure for Selecting New Members of Chartered Study Sections..... | 13 |
| | 1. Rules Regarding Nominations..... | 13 |
| | 2. Identification of Candidates..... | 14 |
| | 3. Preparation of the Nomination Package..... | 15 |
| | E. Invitation to New Members | 16 |
| | F. Orientation of New Members | 17 |
| | G. Procedure for Nominating the Chairperson..... | 17 |
| | H. Liaison Observers from NIH Institutes..... | 17 |
| | I. Observers from Other Government Departments and Agencies | 18 |
| | J. Special Reviewers..... | 18 |
| | K. Annual Study Section Rosters..... | 18 |
| | L. Competency Rosters..... | 19 |
| III. | <u>Study Section Meeting Arrangements</u> | |
| | A. Dates | 33 |
| | B. Locations | 33 |
| | C. Conference Room Requests | 34 |
| | 1. Requests for NIH Conference Rooms..... | 34 |
| | 2. Requests for Non-NIH Conference Rooms in the Washington Metropolitan Area..... | 34 |
| | 3. Requests for Conference Rooms at Out-of-Town Sites..... | 34 |
| | 4. Requests for Telephone Conference Calls..... | 35 |
| | 5. Rooming Lists for Hotels..... | 35 |
| | D. Conference Room Arrangements for Meetings Held Away from NIH..... | 35 |
| | E. Study Section Conferences and Workshops..... | 36 |

IV. Processing of Applications by the Referral Section

| | |
|--|----|
| A. Application Number..... | 55 |
| 1. Application Types..... | 55 |
| 2. Activity Codes..... | 55 |
| 3. Awarding Unit..... | 55 |
| 4. Serial Numbers..... | 56 |
| 5. Suffixes..... | 56 |
| 6. Application Contents..... | 56 |
| B. Receipt, Processing and Assignment of Grant Applications..... | 56 |
| 1. Processing of Type 1, 2, or 3 Applications..... | 57 |
| 2. Processing of Other Types of Applications..... | 59 |

V. Study Section Office: Processing of Applications

| | |
|---|----|
| A. Initial Processing of applications..... | 71 |
| 1. Study Section Log and Application Receipt Record .. | 71 |
| 2. Advance and Work Copies of Applications..... | 71 |
| 3. Study Section Work Record..... | 72 |
| 4. Executive Secretary's Workbook..... | 72 |
| 5. Study Section Records..... | 72 |
| 6. Meeting Files..... | 73 |
| B. Examination of Applications by the Grants Assistant .. | 73 |
| C. Processing New Research Grant Applications (R01)..... | 74 |
| D. Processing of Competing Continuation (2 R01) or Supplemental (3 R01) Research Grant Applications ... | 75 |
| E. Processing of Other Types of Applications | 75 |
| 1. Small Business (SBIR-R43&44) Applications..... | 75 |
| 2. RCDA (K04) and FIRST (R29) Applications..... | 75 |
| 3. AREA (R15) Applications..... | 75 |
| 4. Fellowship (F32) Applications..... | 76 |
| 5. Deferred Applications..... | 76 |
| 6. Change of Study Section..... | 76 |
| 7. Change of Institution..... | 76 |
| 8. PL-480 Applications..... | 77 |
| F. Reprints and Appendices | 77 |
| G. Dual Assignments | 78 |
| H. Distribution of Applications within the Office | 78 |
| I. Revised or Additional Application Pages | 78 |
| J. Revised Budgets | 78 |
| K. Withdrawals | 79 |
| L. Procedure for Making Changes in Applications | 79 |
| 1. Daily Transaction List..... | 79 |
| 2. Submission of Changes..... | 80 |
| M. History Files | 80 |

VI. Review of Applications by the Executive Secretary

| | |
|---|-----|
| A. Assignees and Assignment List | 125 |
| 1. Assignees..... | 125 |
| 2. Assignment List..... | 125 |
| B. Additional Information | 126 |
| C. Outside Opinions | 126 |
| D. Project Site Visits | 127 |
| E. Responsibilities of the Grants Assistant | 127 |

VII. Preparation for Meetings by the Grants Assistant

| | |
|---|-----|
| A. Preparation of Workbooks..... | 161 |
| 1. Mailings | 161 |
| 2. Workbooks for Observers..... | 162 |
| 3. General Mailing Procedures..... | 163 |
| B. Forms Obtained From DRG Computer System..... | 163 |
| 1. Assignment List..... | 163 |
| 2. Scoring Sheets..... | 163 |
| 3. Administrative Data List..... | 163 |
| 4. Worksheets..... | 164 |
| C. Materials Needed During the Meeting | 164 |
| 1. Checklist..... | 164 |
| 2. Seating Chart | 165 |
| 3. Agenda | 165 |
| 4. Rosters..... | 166 |
| D. Transportation of Materials to and from Meeting Site . | 166 |
| 1. Local Meetings..... | 166 |
| 2. Out-of-Town Meetings..... | 166 |
| 3. Hand Carried Materials..... | 167 |

VIII. Role of the Grants Assistant During Study Section Meetings

| | |
|---|-----|
| A. Setting up of the Meeting Room | 187 |
| B. Responsibilities During the Meeting | 187 |
| C. Disposition of Waste Material Following Meetings | 188 |
| 1. NIH Meetings..... | 188 |
| 2. Off-Reservation Meetings | 188 |
| D. Transportation of Essential Review Materials | |
| Back to the Study Section Office | 189 |

IX. Post-Meeting Follow-Up

| | |
|--|-----|
| A. Attendance Record | 191 |
| B. Summary of Data Sheets | 191 |
| C. Calculation of Priority Scores | 191 |
| D. Preparaton of Budget Adjustments..... | 192 |

| | |
|---|-----|
| E. Procedure for Obtaining Summary Statement Tops and Resumes of Recommendations..... | 192 |
| F. Final Accuracy Check..... | 193 |
| G. Release..... | 193 |
| H. Resume of Recommendation, Printing and Distribution... | 193 |

X. Preparation and Distribution of Summary Statements

| | |
|--|-----|
| A. General Information | 197 |
| B. General Guidelines..... | 197 |
| C. Typing Format | 199 |
| D. Special Notes..... | 199 |
| E. Instructions for Text..... | 200 |
| F. Guide for Multiproject Applications..... | 201 |
| G. Roster..... | 201 |
| H. Special Cases..... | 201 |
| 1. Deferred Applications..... | 201 |
| 2. Deferral for Mail Ballot..... | 202 |
| 3. Revised or Corrected Summary Statement..... | 202 |
| I. Distribution of Typed Copies..... | 202 |
| J. Printing Specifications and Distribution..... | 202 |

XI. Study Section Minutes and Conflict of Interest

| | |
|--|-----|
| A. Summary Minutes | 205 |
| 1. Preparation..... | 205 |
| 2. Approval..... | 205 |
| 3. Distribution..... | 205 |
| B. Complete Minutes..... | 206 |
| C. Conflict of Interest Statements | 206 |

XII. Project Site Visits and Other Travel

| | |
|---|-----|
| A. Project Site Visits | 211 |
| 1. Purpose..... | 211 |
| 2. Composition of Site Visit Team..... | 211 |
| 3. Arrangements..... | 211 |
| B. General Travel Information | 212 |
| 1. Object Codes..... | 212 |
| 2. Appropriation Number and Can Number..... | 212 |

XIII. Special Study Section

| | |
|---------------------------------------|-----|
| A. Introductory Comments..... | 221 |
| 1. Project Review and Assignment..... | 221 |

| CHAPTER | PAGE |
|---|-----------|
| B. Administration | 222 |
| 1. General..... | 222 |
| 2. Information Needed Prior to Review..... | 222 |
| 3. Information Needed after Review | 222 XIII. |
| C. Review..... | 223 |
| 1. Study Section Membership..... | 223 |
| 2. Staff Liaison..... | 224 |
| 3. Privacy Act..... | 224 |
| 4. Orientation Document..... | 224 |
| 5. Project Site Visits and SSS Meetings..... | 224 |
| 6. Reporting Actions After the Meeting..... | 225 |
| 7. Reimbursement to Consultants..... | 225 |
| 8. Travel Orders..... | 226 |
| 9. Study Section File..... | 226 |
| 10. Forms..... | 226 |
| XIV. <u>Institute Relationships</u> | |
| A. Role of Institutes in Grant Review..... | 233 |
| B. Materials Required by Institutes from Study Sections . | 233 |
| C. Materials Required by Study Sections from Institutes . | 234 |
| D. Institute Representation at Study Section Meetings and on Project Site Visits | 234 |
| E. Attendance of the Executive Secretary at Council Meetings | 234 |
| XV. <u>Special Information</u> | |
| A. Conflict of Interest | 239 |
| 1. Avoiding Conflicts of Interest in Study Section Assignments..... | 239 |
| 2. Avoiding Conflict of Interest during Study Section Meetings..... | 240 |
| B. Confidentiality | 242 |
| C. Privacy Act..... | 242 |
| D. Freedom of Information Act..... | 244 |
| E. Involvement of Human Subjects..... | 244 |
| F. Animal Welfare..... | 247 |
| G. Hazardous Research Materials and Methods | 249 |
| XVI. <u>General Office Management</u> | |
| A. Cooperation | 251 |
| B. Telephone Calls | 251 |
| C. Attendance | 251 |
| 1. Flexitime..... | 252 |
| 2. Overtime..... | 252 |
| 3. Religious Comptime..... | 252 |
| 4. Executive Secretary's Comptime | 252 |
| D. Study Section Files | 253 |

| CHAPTER | PAGE |
|--|------|
| 1. Overall Guidelines..... | 253 |
| 2. Disposal of Files..... | 254 |
| 3. Material Not Kept in Files After Review..... | 254 |
| E. Supplies and Equipment | 255 |
| 1. Self-Service Store..... | 255 |
| 2. Office Services Section..... | 255 |
| F. DRG Contacts | 255 |
| 1. Civil Service Problems..... | 255 |
| 2. Employee Advisory Committee..... | 255 |
| 3. Equal Employment Opportunity (EEO)..... | 255 |
| 4. Injuries or Accidents..... | 255 |
| XVII. <u>Available Resources</u> | |
| A. Reference Materials | 269 |
| B. Publications | 269 |
| 1. Directories, Rosters, Schedules..... | 269 |
| 2. General Reference Books..... | 270 |
| 3. Extramural Program Policy Guides and Handbooks... | 270 |
| 4. Journals..... | 272 |
| C. Forms..... | 272 |
| D. Equipment..... | 272 |
| E. Speaker Phones..... | 272 |
| F. Computer Aids..... | 270 |
| INDEX..... | 273 |

LIST OF FIGURES

| <u>CHAPTER</u> | <u>FIGURE</u> | <u>PAGE</u> |
|----------------|--|-------------|
| I. | 1. Organization of the Department of Health and Human Services | 5 |
| | 2. Dual Review System for Grant Applications | 6 |
| | 3. DRG Organizational Chart | 7 |
| | 4. Organization Chart of the DRG Referral and Review Branch | 8 |
| II. | 5. Map of the United States | 21 |
| | 6. Snapshot: Record Status Report | 22 |
| | 7. Sample DRG Nomination Memo | 23 |
| | 8. Routing of Waiver Requests | 25 |
| | 9. Professional Area Breakdown | 27 |
| | 10. Letter of Invitation (Study Section Nominees) | 28 |
| | 11. Confirmation Letter | 30 |
| | 12. Request for Approval of Nominee for Chairperson of a Study Section | 31 |
| | 13. Sample Competency Roster | 32 |
| III. | 14. Request for Conference Room Form (NIH 827) | 40 |
| | 15. Notification of Extramural Meeting Form (NIH 2011) | 41 |
| | 16. Memo about Study Section Meeting Dates | 42 |
| | 17. Cost Comparison Form for Out-of-Town Meeting Requests | 43 |
| | 18. Sample Memo Requesting an Out-of-Town Meeting or Workshop | 44 |
| | 19. Memo for Reimbursement for Telephone Conference Call Review | 47 |
| | 20. Consultant Claim Form (NIH 1715-2) | 48 |
| | 21. DRG Policy on Study Section Workshops | 50 |
| | 22. Sample Local Workshop Request Memo | 52 |
| | 23. Sample Pre-Workshop Conference Report | 53 |
| IV. | 24. Activity Codes | 64 |
| | 25. Application Receipt Dates, Review and Award Schedule | 68 |
| | 26. Flow of a Competing Application through the Referral Branch | 69 |
| V. | 27. Project Control Checksheet | 81 |
| | 28. Suggested Study Section Log Format | 82 |
| | 29. Study Section Checksheet | 83 |
| | 30. Human Subjects: 6 Points | 84 |
| | 31. Guidelines for Checking Human Subjects Certification | 85 |
| | 32. Vertebrate Animals: 5 Points | 112 |
| | 33. Request Form for Applicants to Submit Additional Information on Animals Involved in Research | 113 |
| | 34. Request Form for Applicants to Submit Additional Information | 114 |
| | 35. Protection of Human Subjects Form (HHS 596) | 115 |

| <u>CHAPTER</u> | <u>FIGURE</u> | <u>PAGE</u> |
|----------------|--|-------------|
| V.(cont.) | 36. Distribution Chart | 117 |
| | 37. Request for Assignment Change(s) | 121 |
| | 38. Sample Daily Transaction List | 122 |
| | 39. Application/Grant Change Authorization Notice | 123 |
| VI. | 40. Guidelines sent to Reviewers (Guides for Reviewers' Preliminary Comments, Reviews Procedures for IRG Meetings) | 129 |
| | 41. Summary Statement Worksheet | 155 |
| | 42. Assignment List Format | 156 |
| | 43. Sample Additional Information Request Letters | 157 |
| | 43a. Information Request Form for Research Involving Vertebrate Animals | 158 |
| | 44. NIH Conflict of Interest Policy and Certification | 159 |
| | 45. Sample Outside Opinion Request Letter | 160 |
| VII. | 46. Sample Reviewers' Comment Sheet | 169 |
| | 47. Sample Memo Sent to Reviewer with First Mailing | 170 |
| | 48. Sample Agenda | 173 |
| | 49. Sample Study Section Roster | 174 |
| | 50. Memo Requesting Supplies for a Study Section Mailing or Meeting | 176 |
| | 51. Sample Scoring Sheet | 177 |
| | 52. Sample Administrative Data List | 178 |
| | 53. Sample Worksheet | 179 |
| | 54. Sample Assignment List | 180 |
| | 55. Sample Seating Arrangement During Meeting | 181 |
| | 56. Claim for Reimbursement of Travel Cost, Per Diem and Consultant Fee (NIH 1715-2) | 182 |
| | 57. Travel Reimbursement Codes | 183 |
| | 58. Chronological Record of Claims for Travel Reimbursement for Consultants | 184 |
| | 59. Request for and/or Notice of Shipment Form (NIH 1884) | 185 |
| IX. | 60. Attendance Sheet | 195 |
| | 61. Summary of Data: Study Section Review Cycle | 196 |
| X. | 62. Summary Statement Status Report | 203 |
| XI. | 63. Sample Summary of Minutes | 207 |
| | 64. Sample Resume of Initial Review Group Recommendations | 208 |
| | 65. Certification of No Conflict of Interest | 209 |
| | 66. Sample List of Members Absent During Review of Applications | 210 |
| XII. | 67. Travel Order | 213 |
| | 68. Travel Voucher (Standart Form 1012) | 214 |
| | 69. Guide for the Preparation of Project Site Visit Reports | 216 |
| | 70. Request for Travel Reservations (PHS 1558) | 217 |
| | 71. Application for Advance of Funds (Standard Form 1038) | 218 |

| <u>CHAPTER</u> | <u>FIGURE</u> | <u>PAGE</u> |
|----------------|---|-------------|
| | 72. Claim for Reimbursement for Expenditures (Standard Form 1164) | 219 |
| | 73. Authorization to Attend Non-Government Sponsored Meetings | 220 |
| XIII. | 74. Privacy Act Statement (Special Study Section (Reviewers) | 227 |
| | 75. Instructions for Conference Calls | 228 |
| | 76. Claim for Reimbursement of Travel Cost, Per Diem and Consultants Fee (NIH 1715-2): Special Study Sections | 229 |
| | 77. Memo for Reimbursement for Telephone Conference Call Review | 231 |
| XIV. | 78. Sample Notice of Grant Award (PHS 1533) | 237 |
| XV. | 79. Sample Privacy Act Response Letter | 249 |
| XVI. | 80. Record of Congressional Telephone Inquiries (PHS 1553) | 257 |
| | 81. Sample Time Sheet | 258 |
| | 82. Application for Leave (Standard Form 71) | 259 |
| | 83. Memo on DRG Flexitime Procedures | 260 |
| | 84. Request for and Authorization of Overtime (NIH1962) | 266 |
| | 85. Requisition Form for Office Supplies (NIH 20) | 267 |

LIST OF TABLES

| <u>CHAPTER</u> | <u>TABLES</u> | <u>PAGE</u> |
|----------------|-------------------------------|-------------|
| I. | 1. Referral and Review Branch | 9 |
| III. | 2. No Charge Conference Rooms | 39 |
| IV. | 3. Types of Applications | 61 |
| | 4. Awarding Units | 62 |
| | 5. Grant Application Kits | 63 |

Chapter I

I N T R O D U C T I O N

A. THE NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health (NIH) is the principal medical research arm of the Federal Government and one of the six health agencies of the Public Health Service (PHS), which is a component of the Department of Health and Human Services (DHHS). Included within the NIH are 20 Bureaus, Institutes, and Divisions. Those that are funding organizations will hereafter be referred to as "Institutes." Most of the NIH is located in Bethesda, Maryland, although the National Institute of Environmental Health Sciences is in Research Triangle Park, North Carolina, the intramural program of the National Institute on Aging is in Baltimore, Maryland, and some research components of the NIH are located in other areas of the United States. Figure 1 shows the general organization of the NIH and its position within DHHS.

The mission of the NIH is to improve the health of the Nation by increasing our understanding of the processes underlying human health and by acquiring new knowledge to help prevent, detect, diagnose, and treat disease.

The NIH accomplishes this mission by:

- supporting research in universities, medical schools, hospitals, and research institutions in this country and abroad;
- conducting research in its own laboratories and clinics;
- supporting training for promising young researchers;
- helping to develop and maintain research resources;
- identifying research findings that can be applied to the care of patients, and helping to transfer such advances to the health care system;
- promoting effective ways to communicate biomedical information to scientists, health practitioners, and the public; and
- developing and recommending policies related to the conduct and support of biomedical research.

In order to achieve these goals, the NIH relies on its intramural and extramural programs. The intramural programs support biomedical and clinical research projects conducted at the NIH, while the extramural programs provide funding for investigators at other institutions.

B. EXTRAMURAL FUNDING

The diverse funding mechanisms for extramural research are divided into three main categories: grants, contracts and cooperative agreements. In general, with grants, the applicant investigator is responsible for developing the concepts, methods, and approach for a research project; with contracts, however, the awarding Institute is responsible for establishing the plans, protocol, and detailed requirements for a project. Contracts are normally solicited through requests for proposals (RFPs), while grants are not usually solicited. In certain circumstances, however, grants are solicited to support areas of special interest to an awarding unit, in which case requests for applications (RFAs) or program announcements are issued. The cooperative agreement is to support or stimulate the recipient's activities, but also provides for substantial involvement on the part of the funding agency during the period of performance.

Grant applications are classified according to type, such as new, competing continuation (renewal), and supplemental applications, and according to activities, such as individual research projects, conferences, program projects, centers, Research Career Development Awards, First Independent Research Support and Transition Awards, and fellowships. Contract proposals are classified according to transaction types, such as new, renewal, modification, and continuation of incrementally funded contracts.

All three funding mechanisms of support--grants, contracts, and cooperative agreements--may be awarded to both non-profit and for-profit organizations.

C. HOW A RESEARCH GRANT IS AWARDED

An investigator, usually through his institution or research center, submits a grant application to the NIH. The application is sent to the Referral Section, Division of Research Grants (DRG), which is the central point for the initial processing and assignment of grant applications. If the application is relevant to the NIH mission, a Referral Officer assigns it to an Initial Review Group and to one or more Institutes.

The grant application is first reviewed for scientific merit by a panel of experts, primarily non-Government scientists from academic or research organizations throughout the United States. Depending on the type of application, the review group will be either from DRG or from one of the Institutes. These review groups may be referred to as Scientific Review Groups (SRGs), if they review both grant applications and contract proposals, or Initial Review Groups (IRGs), if they review only grant applications. Within DRG, such groups are generally called Study Sections.

The second level of review is by National Advisory Boards or Councils, hereafter called "Councils," composed of both scientific and lay representatives who are noted for their expertise, interest, or activity in matters related to health and disease. Council recommendations are based not only on considerations of scientific merit as judged by an IRG, but also on the relevance of a grant application to an Institute's programs and priorities.

Councils can reverse an approval or disapproval action by an IRG on the basis of policy or a minority report; they cannot reverse an action based on science. Usually Councils will request a rereview of an application by the same or another study section when they feel a review was not valid.

By separating the scientific assessment of proposed projects from policy decisions about scientific areas to be supported and the level of resources to be allocated, the dual review system permits a more objective evaluation than would result from a single level of review (Figure 2). This system provides the appropriate NIH officials with the best available advice about scientific expertise as well as societal values and needs.

THE DIVISION OF RESEARCH GRANTS

As a support division of the NIH, DRG:

- receives and processes applications submitted to the Public Health Service (PHS), and assigns such applications to IRGs for scientific merit review and to awarding organizations for possible funding;
- provides the scientific merit review of most NIH grant applications;
- collects, stores, retrieves, analyzes, and evaluates management and program data needed in the administration of NIH extramural programs;
- advises the Office of Extramural Research and the Office of the Director, NIH, in the formulation of grant application review policies and procedures; and
- disseminates information on NIH extramural programs to the scientific community and the general public.

The DRG internal structure is shown in Figure 3, and the functions of each of the major offices and branches are explained in Manual Issuance 1125. Organizationally, DRG is accountable to the Office of the Director, NIH, and is separate from the other Institutes. DRG does not itself fund or manage grant programs.

This Handbook discusses in detail the activities and responsibilities of the Review Sections of the Referral and Review Branch (RRB). (See Figure 4 for the internal structure of this Branch.) Specifically, the Branch manages 90 plus study sections organized basically along scientific disciplines and medical specialty areas (Table 1). Each study section consists of consultants who are primarily non-Government scientists drawn from academic and research organizations, and is under the direction of an Executive Secretary, who is a full-time DRG Health Scientist Administrator.

A Grants Assistant and sometimes a Grants Clerk assist each Executive Secretary in the administration of study section activities.

Although basic secretarial-clerical skills are required, there is constant, challenging on-the-job training. The Grants Assistant, who works directly with the Executive Secretary, is primarily responsible for the effective management of the study section office, and has the opportunity to become closely involved with many of the professional aspects of study section work. The following chapters describe these responsibilities.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

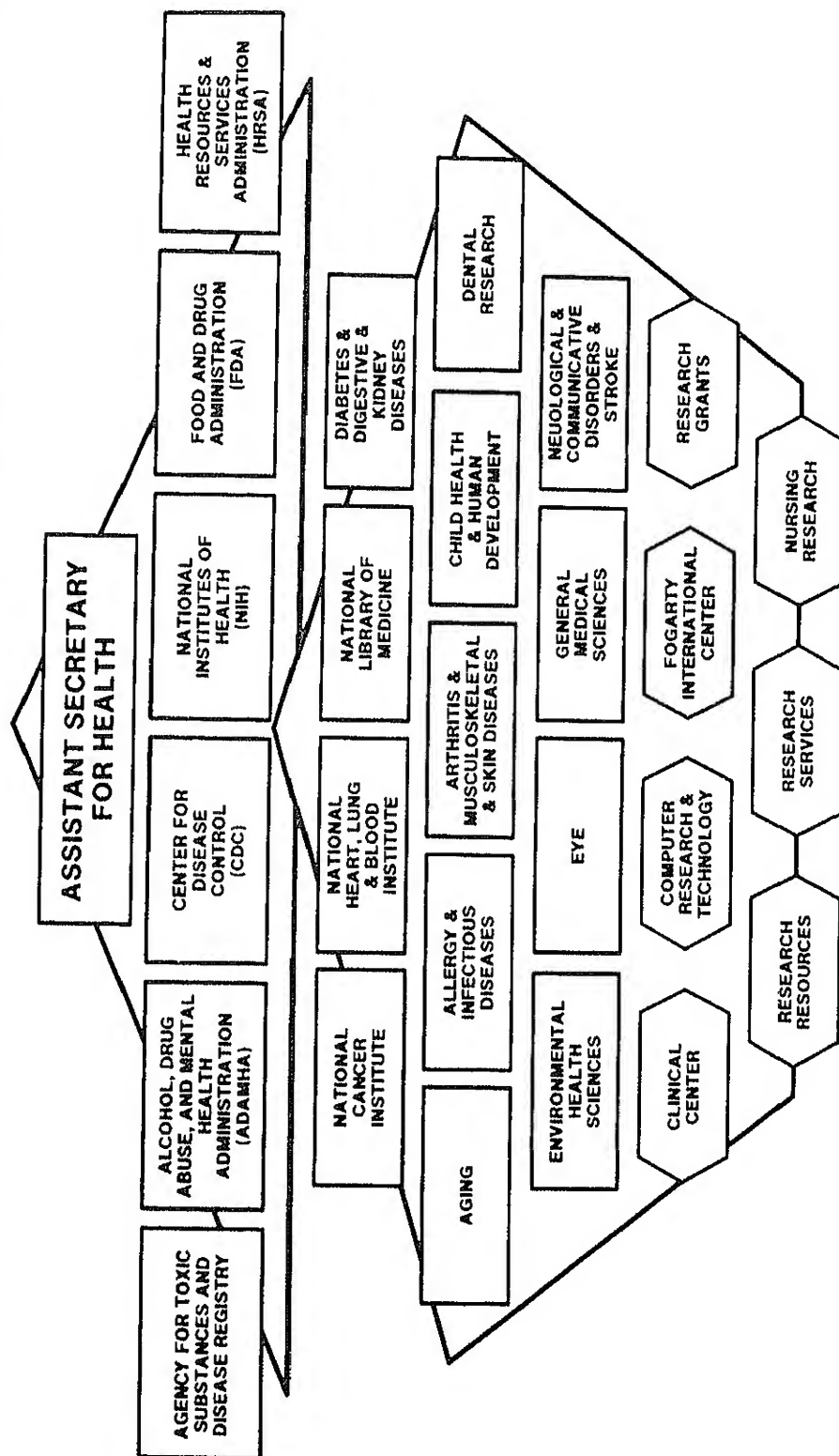


FIGURE 1

DUAL REVIEW SYSTEM FOR GRANT APPLICATIONS

FIRST LEVEL OF REVIEW

INITIAL REVIEW GROUP

- PROVIDES INITIAL SCIENTIFIC REVIEW OF GRANT APPLICATIONS
- DOES NOT SET PROGRAM PRIORITIES
- MAKES BUDGET RECOMMENDATIONS BUT NO FUNDING DECISIONS

SECOND LEVEL OF REVIEW

COUNCIL

- ASSESSES QUALITY OF SRG REVIEW OF GRANT APPLICATIONS
- MAKES RECOMMENDATIONS TO INSTITUTE STAFF ON FUNDING
- EVALUATES PROGRAM PRIORITIES AND RELEVANCE
- ADVISES ON POLICY

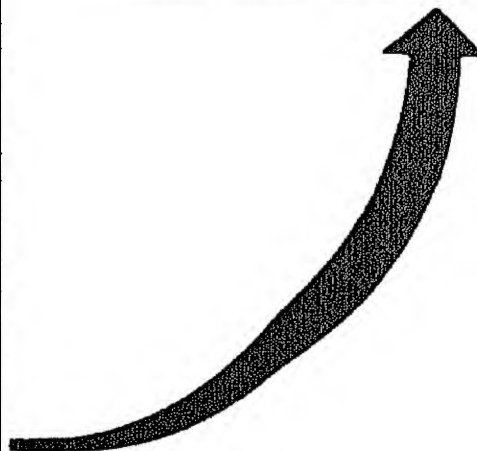


Figure 2

Figure 3

Figure 3

DRG ORGANIZATIONAL CHART*

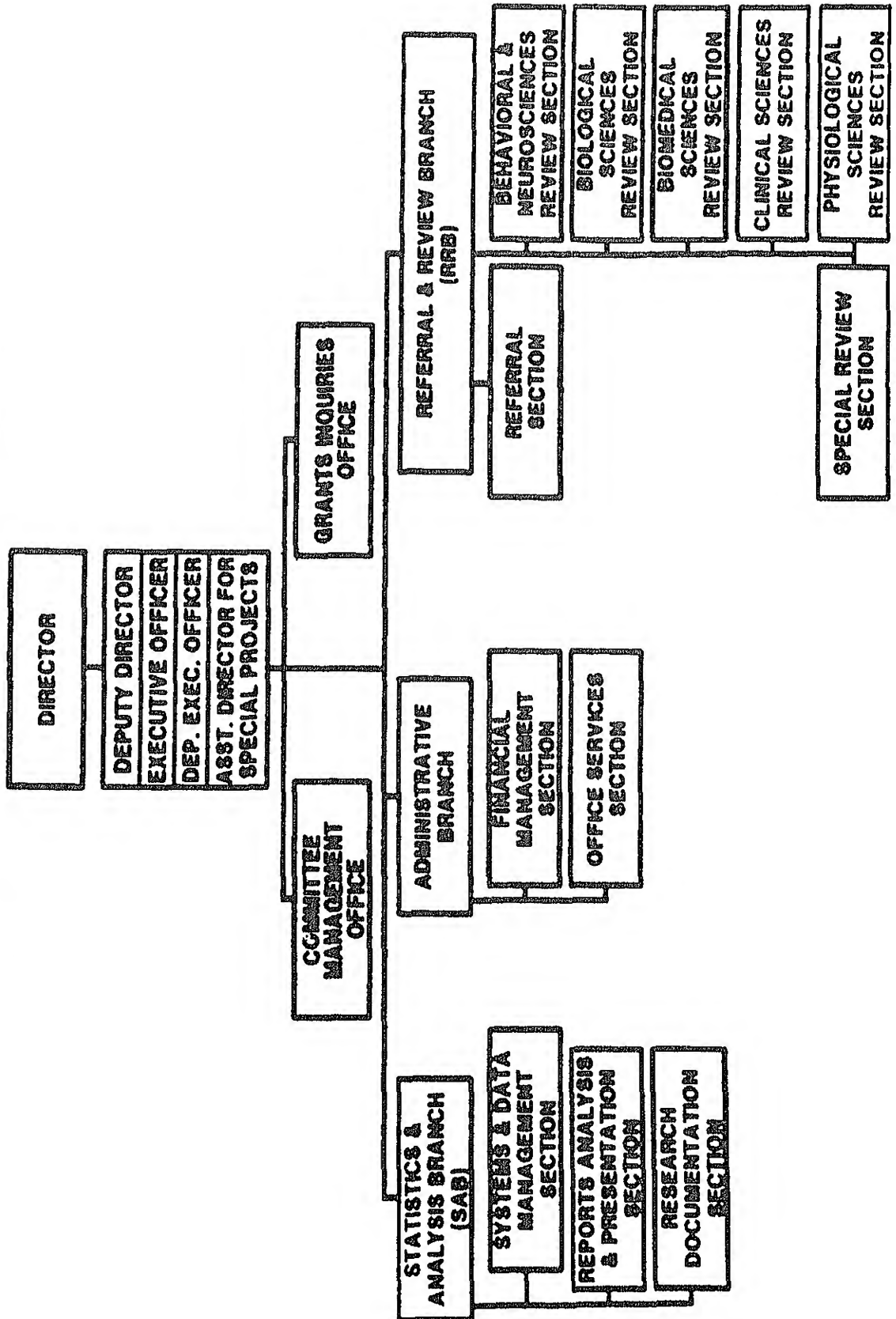


Figure 4

ORGANIZATIONAL CHART OF THE DRG REFERRAL AND REVIEW BRANCH

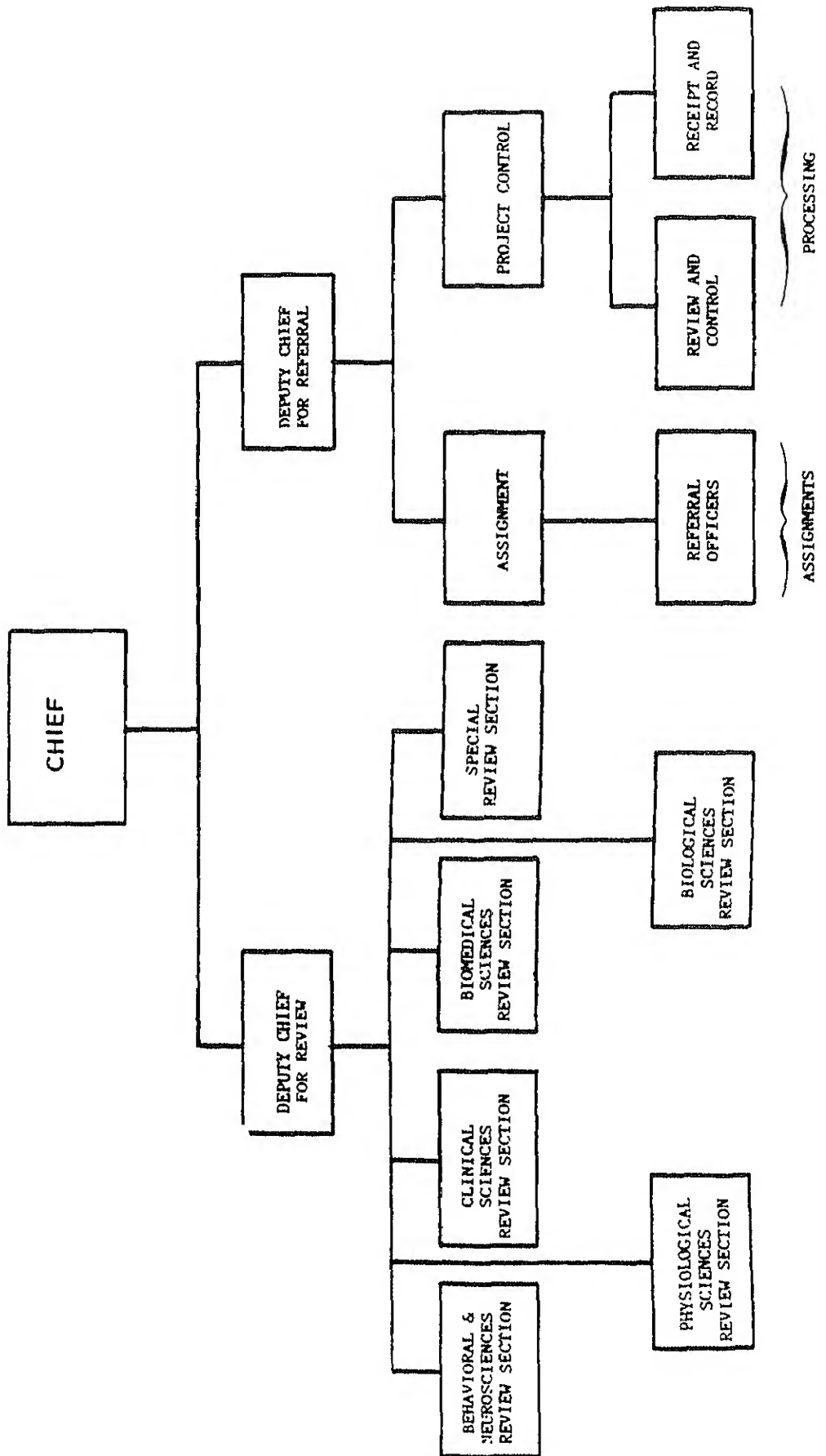


TABLE 1. REFERRAL AND REVIEW BRANCH
 Chief, Dr. Mischa Friedman+
 Acting Deputy Chief, Dr. Raymond Bahor
 Deputy Chief for Referral, Dr. Patricia Straat
 Institute Liaison Program Analyst, Nicholas C. Moriarity, Jr.

BEHAVIORAL AND NEUROSCIENCES REVIEW SECTION

Chief, Dr. Samuel Rawlings
 Lead Grants Technical Assistant,
 Jenny Bogley

AFL Adolescent Family Life (AHR)*
 BEM Behavioral Medicine
 BNS 1 Neurological Sciences (Fellowships)
 BNS 2 Psychology & Social Sciences "
 BNS 3 Communicative Sciences "
 BPO Bio-Psychology
 CMS Sensory Disorders and Language
 HAR Hearing Research
 HUD 1 Human Development and Aging 1
 HUD 2 Human Development and Aging 2
 HUD 3 Human Development and Aging 3
 NEUA Neurology A
 NEUB 1 Neurology B 1
 NEUB 2 Neurology B 2
 NEUC Neurology C
 NLS 1 Neurological Sciences 1
 NLS 2 Neurological Sciences 2
 SDI Service Delivery Improvement (AHR)*
 SSP Social Sciences & Population
 VISB Visual Sciences B

BIOMEDICAL SCIENCES REVIEW SECTION

Chief, Dr. Asher Hyatt
 Lead Grants Technical Assistant,
 Virginia Shifflett

BBCA Molecular & Cellular Biophysics
 BBCB Biophysical Chemistry
 BI 1 Genetics (Fellowships)
 BI 2 Biochemistry & Pharmacology "
 BI 4 Biophysical & Bio-organic Chemistry "
 BI 7 Genetics (Fellowships)
 BIO 1 Biochemistry 1
 BIO 2 Biochemistry 2
 BMT Metallobiochemistry
 BNP Bio-organic & Natural
 Products Chemistry
 GEN Genetics
 MCHA Medicinal Chemistry
 MET Metabolism
 MGN Mammalian Genetics
 NTN Nutrition
 PB Physical Biochemistry
 PBC Pathobiochemistry
 PC Physiological Chemistry
 RAD Radiation

BIOLOGICAL SCIENCES REVIEW SECTION

Chief, Dr. Hugh Stamper
 Lead Grants Technical Assistant,
 Linda Robbins

ALY Allergy & Immunology
 BI 3 Cellular & Molecular Biology (Fellowships)
 BI 5 International Awards (Fellowships)
 BI 6 Cellular & Molecular Biology (Fellowships)
 BM 1 Bacteriology & Mycology 1
 BM 2 Bacteriology & Mycology 2
 CBY 1 Cellular Biology & Physiology 1
 CBY 2 Cellular Biology & Physiology 2
 CLIN 1 Immunology and Virology (Fellowships)
 CTY Molecular Cytology
 EI Experimental Immunology
 EVR Experimental Virology
 IMB Immunobiology
 IMS Immunological Sciences
 MBC 1 Microbial Physiology & Genetics 1
 MBC 2 Microbial Physiology & Genetics 2
 MBY Molecular Biology
 TMP Tropical Medicine & Parasitology
 VR Virology

*Ad Hoc Review Group

+Also Associate Director for Referral and Review, DRG

LICAL SCIENCES REVIEW SECTION

Chief, Dr. Nathan Watzman
Lead Grants Technical Assistant,
Betty Lester

- 2 Physiological & Cardiovascular Sciences (Fellowships)
- 4 Clinical Pathological Sciences (Fellowships)
- Chemical Pathology
- Cardiovascular & Pulmonary
- Cardiovascular & Renal
- Experimental Cardiovascular Sciences
- 1 Epidemiology & Disease Control 1
- 2 Epidemiology & Disease Control 2
- 1 General Medicine A 1
- 2 General Medicine A 2
- 1 Hematology 1
- 2 Hematology 2
- Metabolic Pathology
- 5 Nursing Research
- 4 Orthopedics & Musculoskeletal
- 4 Pathology A
- 3 Pathology B
- Respiratory & Applied Physiology
- Diagnostic Radiology
- Surgery, Anesthesiology & Trauma
- Surgery & Bioengineering

SPECIAL REVIEW SECTION

Chief, Dr. Jeanne Ketley
Lead Grants Technical Assistant,
Ms. Genevieve Pearsall

- SSS 0 to SSS 9, SSS W, SSS X, SSS Z
- SSS H (HLS; History of Life Sciences Review Group)

IOLOGICAL SCIENCES REVIEW SECTION

Chief, Dr. Faye Calhoun
Lead Grants Technical Assistant,
Jane Martin

- Biochemical Endocrinology
- 3 Endocrinology & Reproductive Biology (Fellowships)
- Endocrinology
- 1 Experimental Therapeutics
- 2 Experimental Therapeutics
- General Medicine B
- Human Embryology & Development
- yology & Development (AHR)*
- w & Medicine 1
- & Medicine 2

Chapter II

S T U D Y S E C T I O N S

A. STUDY SECTION OFFICE

Each study section office consists of an Executive Secretary, a Grants Assistant, and possibly a Grants Clerk. They share responsibility for ensuring that applications in their specific scientific area are processed correctly, that all necessary materials are obtained and mailed to study section members, that the meetings of the study section are held and reported on in detail, and that summary statements with the study section recommendations are prepared for transmission to the Institutes. A current list of the study sections, Executive Secretaries, and staff is distributed at regular intervals.

B. STUDY SECTION MEMBERSHIP

Each study section is composed of a panel of scientific consultants qualified to evaluate applications in a particular area of biomedical science. While study sections are normally composed of 16 to 20 members, this number may increase if the workload and diversity of applications require a larger number of specialists. The responsibility for choosing the members of a study section rests with the Executive Secretary, who uses many sources in the selection process. The Handbook for Executive Secretaries describes more fully the composition and selection of study section membership.

C. TYPES OF STUDY SECTIONS

1. Chartered Study Sections

- a. Regular Study Sections. All NIH public advisory committees are established under Section 222 of the Public Health Service Act, as amended by 42 US Code 217a. Regular study sections are chartered by the Director, NIH, in accordance with P.L. 99-158. Requests for charter renewals are handled by the DRG Committee Management Office (CMO). The number of members on a chartered study section is established in the charter.

Members normally serve for 4 years, with the term of office usually beginning July 1 and always ending on June 30. If, for unusual reasons, an appointment is initiated mid-year, the term still terminates on June 30. Appointments are staggered so that about one-fourth of the membership of a study section are new each year. New nominations are initiated about a year in advance.

- b. Flexible Study Sections A flexible study section is chartered with the provision for a large number of members and a subcommittee structure. The membership can be either (1) subdivided into as many subcommittees as needed to review applications, or (2) subdivided into a fixed number of subcommittees, each operating as a regular study section.
- c. Fellowship Study Sections Fellowship applications are generally reviewed by flexible study sections that consist of up to 64 members, including the Chairperson, and are subdivided into four or five subcommittees organized according to specific areas of research. Those procedures for nominating and appointing members and the arrangements for meetings parallel those of the research grant study sections.

2. Ad Hoc Study Sections

Ad hoc study sections are not chartered study sections but are organized, as needed, for review of applications. However, the reviewers and Chairperson for these meetings are chosen, by the Executive Secretary assigned to the meeting, using the same criteria and in accordance with the rules for chartered study sections. The payment for the operation of ad hoc study sections is made from the Chairperson's Scientific Review and Evaluation Award of a chartered study section. (See Section G. Procedure for Nominating a Chairperson.)

- a. Overflow When the workload for a chartered study section becomes excessive for any one round, the Executive Secretary of the study section, with the consent of the Section Chief and Deputy Chief for Referral, may form an ad hoc group to review the excess applications - AHR F (F for overflow).
- b. Special When an Executive Secretary is assigned a "Special," the review group constituted for that purpose would be designated AHR S (S for special review group), which delineates a review of applications not involving members of study sections. (This is not to be confused with SSS - Special Review Section.)
- c. SBIR The Small Business Innovation Development Act requires the PHS to set aside a specific amount of its research and development budgets for a Small Business Innovation Research (SBIR) Program. The ad hoc review group reviewing the small business applications would be designated AHR B (B for small business).
- d. Member The Executive Secretary forms a special committee to review an application involving a member of another study section, thus avoiding a conflict of interest for the original study section. The new group would be designated AHR M.

- e. AREA The Executive Secretary assigned AREA applications (research applications from small colleges and minority institutions) would set up a committee AHR A (A for AREA).
- f. Continuing Ad Hoc Review Committees When a new scientific area has been developed and a committee is formed, or when an established committee is seeking a charter, they are designated as continuing ad hoc review groups. They review applications on a regular cycle. These review groups would include AHR as part of their title.
- g. SSS The Special Review Section is comprised of ad hoc committees. These committees regularly review program project grant applications, applications from research centers, research resource grants, instrumentation grant applications, SBIR applications, and other specialized applications. At least 5 consultants are needed to review any SSS application, and up to 20 consultants are invited for more complex applications or when several applications are being reviewed. Expenses for SSS committees are paid by the Chairperson's Scientific Review and Evaluation Award of a chartered study section on a rotating basis among all chartered study sections.

D. PROCEDURE FOR SELECTING NEW MEMBERS OF CHARTERED STUDY SECTIONS

1. Rules Regarding Nominations

- a. Deadlines for Submitting Nominations. July 1 is the earliest date that a study section office is permitted to submit nominations for the following year. The deadlines for each Review Section change each year, but occur on approximately November 1, November 18, and December 1. Approval of nominations takes from 4 to 6 months.
- b. Female and Minority Representation. NIH's goal is to maintain approximately 23 percent female and 17 percent minority representation on all NIH public advisory committees. Therefore, if the continuing female and minority membership falls below these percentages, a female and a minority candidate must be included on the nomination slate. If this is not possible, a written waiver request is to be submitted stating the specific areas of expertise needed and the efforts made to find an appropriate female or minority candidate.
- c. Geographical Distribution. Selection of candidates shall reflect equitable representation of all geographic regions of the United States.

Nominees should be selected from consultants living in the continental United States, Alaska, Hawaii, or Puerto Rico. Canadians may also be nominated. No more than 15 percent may be from New York, Massachusetts, Texas, or California.

Membership exceeding 15 percent from these states requires a waiver request. All other states are limited to 10 percent. Fifty percent is the limit permitted from any general geographic area. (See Figure 5, Map of Regions.)

- d. Two Members from the Same Organization. Two members cannot be from the same Institution. A waiver of Department policy for having two members from the same institution may be considered if highly specialized expertise is needed or if a highly qualified minority or woman candidate can be identified. The nominees must work in different departments, their work must be unrelated, and they cannot be involved in the same areas of review. Also, a nominee cannot replace a retiring member from the same institution, unless the Section Chief grants an exception. A wait of 1 year is required before appointing another member from the same institution.
- e. Federal Employees. Each study section may normally have only one Federal employee as a member. Additional Federal employees may be nominated in very special cases and only with the approval of the Section Chief.
- f. For-Profit Members. Nominees from for-profit organizations are allowed. However, only one person from an organization, regardless of location, may be nominated.
- g. Terms of Appointment. As previously noted, a term is limited to 4 years, although a waiver can be granted for a 5th year of service. Under the Public Health Service Act, no committee member may be reappointed to serve on the same or any other committee until at least 1 year has elapsed unless a waiver is requested by the Director, DRG, and is approved by the Director, Secretary's Advisory Committee Office.

If an individual has previously served 8 years in the past 12 years, a waiver for excessive service is required. An early resignation may be replaced by a full 4-year nominee if this does not upset the rotation of termination dates. The term begins after the nomination has been approved, but must end June 30 of the fourth year.
- h. Conflict of Interest. Final approval of any nominee is contingent upon the review of the completed Form HHS-474, "Confidential Statement of Employment and Financial Interest," for actual and apparent conflicts of interest. The forms must be reviewed and signed by the Executive Secretary and the Director, DRG. A review of the form by the Director, NIH, is required if the member is a full-time employee of a for-profit organization.

2. Identification of Candidates

In order to obtain names of qualified potential study section members, the Grants Assistant can assist the Executive Secretary by initiating scientific literature searches accessing DIALOG, MEDLINE, TOXLINE, CHEMLINE and CANCERLIT. (For "how to" information, contact the User Resource Office.) Also, a request for a search of names by specific research areas can be obtained by accessing the Committee Management Information System (CMIS). Additional information regarding this source is available in the CMO.

After the Executive Secretary has provided the Grants Assistant with the information needed on each candidate, the Grants Assistant should go to the CMO to pick up all required forms and check the alphabetical listing of consultants to be sure the candidate is not serving on another NIH committee.

In addition, the Grants Assistant may use RAID (Random Access for Institutes and Divisions) for retrieval of Institute data from the IMPAC system's master files and data bases to obtain a SNAPSHOT (Figure 6) of the candidate's affiliation to NIH. (Contact the User Resource Office for instructions.)

3. Preparation of the Nomination Package

- a. DRG Nominating Memo. The Grants Assistant prepares a DRG Nomination Memo, which lists all candidates (in alphabetical order), term dates, and a brief description of their scientific expertise. The preferred source for the CV and publications is a recent (within 3 years) biographical sketch from a grant application. If a biographical sketch is not available or is not current, an updated personal CV with publications must be obtained from the candidate. Pertinent information must be extracted from the personal CV and typed onto the Alternate CV Form. Do not include the complete personal CV. Publications from the personal CV should accompany the Alternate CV Form.
- b. Nomination Package. The nomination package, with all the required forms and copies for the appropriate Institutes, are to be forwarded to the CMO through the appropriate Section Chief. A concurrence slip, signed by the Section Chief, must be attached to the packet before it is submitted to the CMO. When forwarding nominations to the Section Chiefs, include the appropriate number of Institute copies as well as a copy for the CMO. Do not send Institute copies directly to the Institute. For the Institutes, two copies of the nomination memorandum and attachments (CVs and publications) are required. The CMO then forwards an Availability Check Request (ACR) card for each nominee to the NIH CMO in Building 1, for submission to the Department CMO for a thorough check as to past or present service on

any other HHS committee. At the same time, the ACR cards are sent to the Building 1 CMO, DRG sends the nomination memo and attachments to the appropriate Institutes for review.

- c. Form NIH/CMO 08/01/84 "Request for Approval of Nominees for Public Advisory Committees." The Grants Assistant completes Form NIH/CMO 08/01/84 for each nominee (Figure 7). This form must be signed by the Director, DRG, and the Director, NIH, which indicates their approval for the nominee to be invited to serve.
- d. Waiver Requests. Waivers may be requested for exceptions to such regulations as the lack of female and minority study section members or excessive service. (See the list of the types of waivers in Figure 8). For exemptions to Department and NIH policies, waiver requests must be prepared by the Executive Secretary and included in the nomination package (Figure 8). A waiver request should include the following information:
 - sources used to identify potential candidates, such as membership rosters of professional societies, past and present study section members, appropriate persons in the relevant Institutes, etc;
 - information regarding scientific areas needing coverage and difficulties in locating candidates; and
 - names of scientists identified and the reasons they are not being nominated.

Note: Waiver requests are reviewed carefully and critically. To avoid delays, waiver requests must be fully justified and explained. Samples of waiver requests are available in the CMO.

- e. Professional Area Breakdown. The Executive Secretary should develop a professional area breakdown, which lists: retiring and continuing members by term-ending dates, areas of scientific expertise, geographic location, and female and minority status; and the proposed replacements for retiring members, or vacancies by term ending dates, areas of scientific expertise, geographic location, and female and minority status (Figure 9).
- f. Grant ID Record. The nomination package must include a copy of a candidate's NIH grant history if available. Instructions for obtaining this information are available in the CMO.

NOTE: Current Instructions and Samples for Nominations are Available in The Committee Management Office.

E. INVITATION TO NEW MEMBERS

and rankings. If
etary checks with

Once the nomination of a new study section member has in the CMO for at various levels of the NIH, a letter of invitation (i) prepared by the CMO and signed by the Director, DRG, required forms and informational materials are mailed with letter, including the HHS-474 Confidential Statement of Employment and Financial Interests and a CV Form. On the CV, nominees should be areas of their scientific and professional competence, interests of and experience. This information aids the Executive Secretary in assigning applications for review and also provides data for the annual Rosters of NIH Initial Review Groups. The nominee replies by returning the required forms to the CMO. Form HHS-474 is reviewed and when approved, signed by the Director, DRG. A follow-up letter is prepared by CMO and signed by the DRG Committee Management Officer (Figure 11).

F. ORIENTATION OF NEW MEMBERS

After the nominee accepts the invitation, the Executive Secretary usually writes to welcome the new member and to describe in more detail the activities of the study section. The new member is also sent the current Orientation Handbook for Members of Scientific Review Groups and the latest edition of the NIH Public Advisory Groups: Authority, Structure, Functions, Members. If an acceptance is received prior to the June meeting, the new member may be invited to attend one day as an observer or a special reviewer. This visit provides the new member with an opportunity to learn about the review procedures first-hand before active participation at the October-November meeting.

G. PROCEDURE FOR NOMINATING THE CHAIRPERSON

The Chairperson of a study section is usually selected from the present membership. Occasionally a former study section member may be appointed. If selected from the present membership, the members usually serve as Chairperson for the remainder of their term, e.g., 1 or 2 years (Figure 12).

The Executive Secretary nominates a Chairperson at least 6 months before the expiration of the term of the present Chairperson by sending a memorandum and a Request for Approval Form to the CMO through the appropriate Section Chief. A nomination memorandum is prepared by the CMO for the signature of the Director, DRG, and sent to the Director, NIH, for approval. When the nomination is approved by the Director, NIH, the CMO prepares an invitation letter for signature of the Director, DRG.

When Chairpersons accept by returning an acceptance form to the CMO, they are awarded a Scientific Review and Evaluation Award, handled through the Federal Credit Union. This award is used to pay for travel, consultants' fees, and per diem of the study section members during project site visits and regular study section meetings; meeting rooms; and special expenses incurred in connection with

conferences and workshops. The management of this award is the responsibility of the Chairperson and the Executive Secretary.

H. LIAISON OBSERVERS FROM NIH INSTITUTES

The study section staff and the appropriate Institute staff share the responsibility for seeing that the scientific merit review and subsequent decision on funding of an application are handled in an equitable and professional manner. The relationship should, therefore, be a cooperative one with each freely consulting the other to seek advice about or resolve any conflicts over an issue.

The Grants Assistant's responsibilities include:

- notifying the Institute staff of changes in application status before the study section meeting;
- tracking and sending to the Institute all correspondence and additional materials received from applicants;
- sending to the Institute, in a timely manner, a copy of the complete summary statement for each application after the study section meeting; and
- notifying the Institute of the time and place of site visits.

A staff member from the Institute served by the study section usually attends the study section meeting to observe the discussions of the study section and to act as a source of information on Institute policies and programs.

I. OBSERVERS FROM OTHER GOVERNMENT DEPARTMENTS AND AGENCIES

Certain Government departments and agencies, such as the Department of Defense (Air Force, Army, Navy), Veterans Administration, and Food and Drug Administration, may wish to send observers to study sections. After first receiving permission from the Executive Secretary, each department or agency may send one observer per study section. These observers do not participate in the meeting or review applications.

J. SPECIAL REVIEWERS

Ad hoc individuals may serve as special reviewers at meetings of chartered study sections. They are valuable resources to the study section, supplementing the capabilities of the membership by providing special expertise in required areas. These special reviewers may provide written and oral opinions and discuss the merits of any items under consideration, but may not vote on the actions and recommendations developed by the study section nor record ratings, scores, or rankings concerning applications, proposals, or projects. If these reviewers are members of the NIH Reviewers Reserve, they may vote on study section actions and

recommendations, and record ratings, scores and rankings. If special reviewers are needed, the Executive Secretary checks with the listing of NIH study section members held in the CMO for possible candidates.

K. ANNUAL STUDY SECTION ROSTERS

Reference copies of chartered study section rosters should be maintained in the study section office at all times. All rosters of chartered study sections are published semiannually in NIH Public Advisory Groups: Authority, Structure, Function, Members.

L. COMPETENCY ROSTERS

The Grants Assistant compiles a study section competency roster (Figure 13) each August and submits a copy to the CMO, DRG. The members are listed alphabetically as they appear on the study section roster; next to each name are the year their term ends and area of competence, with descriptive titles rather than sentences. The special competencies of members of review groups are listed in the Competency Rosters of NIH Initial Review Groups which is issued annually by the Referral and Review Branch, DRG. Reference copies should be maintained in the study section office.

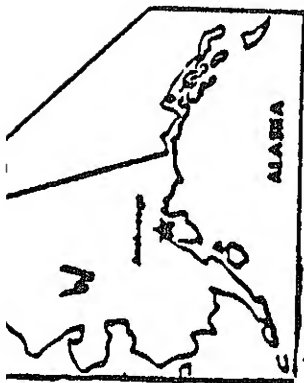
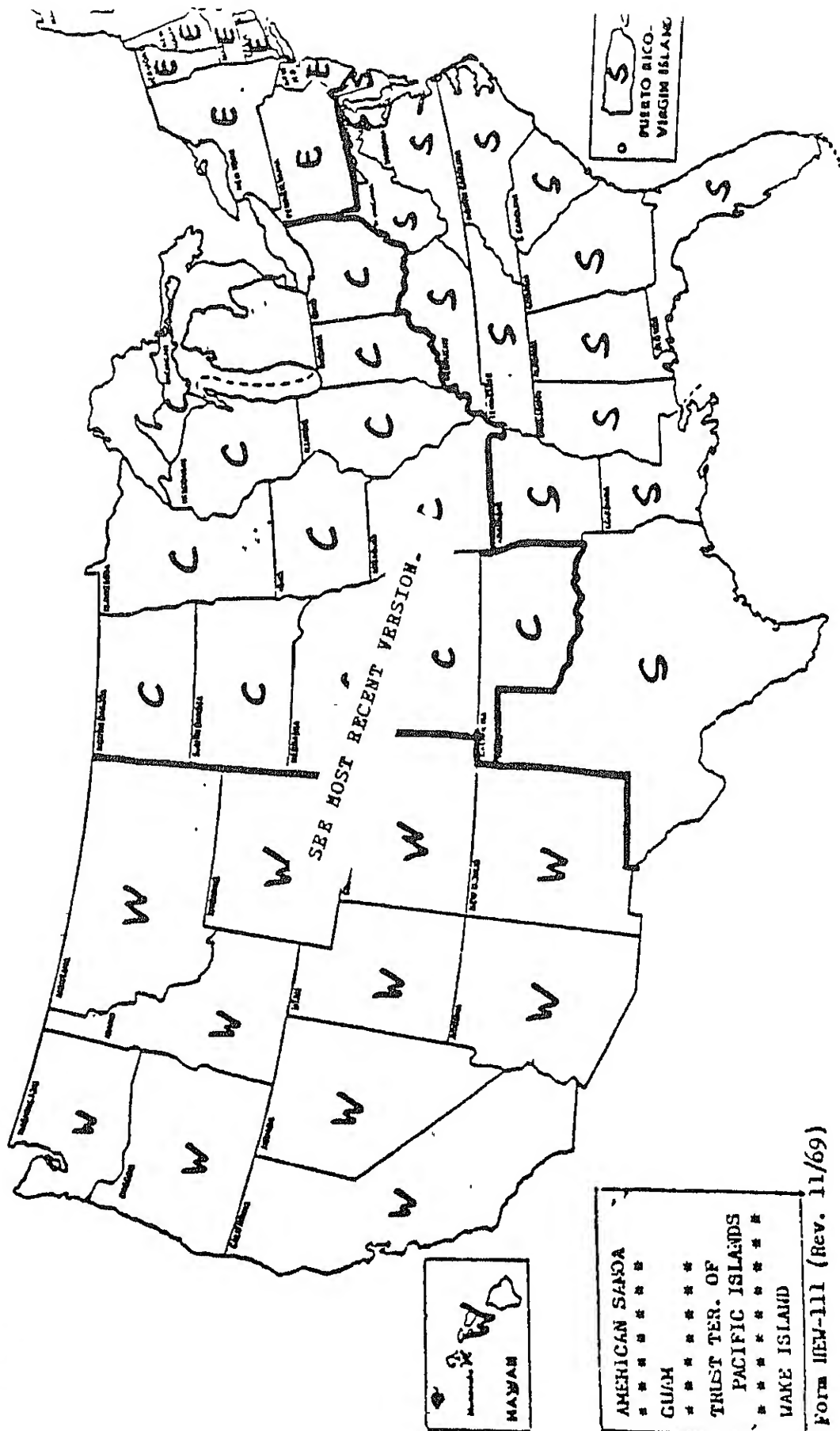


FIGURE 5

THE UNITED STATES OF AMERICA
AND ITS TERRITORIES AND POSSESSIONS
(Outline Map)



APPLICATION/GRANT FORMATS

FORMAT A

The first line displays the applicant/awardee name and institution. The second line shows the requested start date, project title, program class code (091), and an "S" if the record is a skeleton (item 380 = S). The third line displays the file location (0 or P), record ID, IRG (items 5, 305, 38, 138), former number (item 6), and direct cost (120).

The fourth line displays the appropriate status message (see pages 24).

```
LABBOTT, JOAN
ST 02/01/82 PHENOTYPE ANALYSIS OF T LINEAGE DEVELOPMENT IN VITRO PC: 12345678
0 5R01AI12345-03 IMS DC: 12,973
AWD 101,934, 0 FUT YRS 02/01/82 TO 01/31/83, ENC 03/02/82
```

FORMAT B

The first line displays the IRG, Flexible IRG designator code, special IRG (if AHR), group code, record ID, co-funding indicator, former number, council meeting date. (Items 005,305,038,138,001,002,003,004,006,007 respectively) If an application is to be reviewed by more than one BID, a line will be inserted between line 1 and 2 that will reveal the dual BID'S as well as the Dual Program Class Code. (Item 004 204 391) The second line displays applicant/awardee name, social security number, program classification code, and Council recommendation. (Items 009,082,091,065 respectively) The third line displays file location (0 or P), institution, institution city, state and priority score. (Items 017,018,043 respectively) The fourth line displays whether the applicant has completed studies or degrees related to nursing, up to 3 degrees, irg priority score percentile and reference code. (Items 130 10 310 225). The fifth line displays project title, entity number. (Items 019, 131) The sixth line displays start date 1, end date 1, start date 2, end date 2, encumbrance date. Items (041,021,020,090,113 respectively) The seventh line displays the appropriate status message (see pages 24).

```
IMS
LABBOTT, JOAN 5 R01 AI12345-03 199-555-1212 PC: 02X650I CNCL: 00/81
0 SLOAN-KETTERING INSTITUTE FOR CANCER RES NEW YORK IPF:1234567 PS: 183 CA:
NRS RLTY DEG:BS IMS :PHD PCNT: 74.8 REF CD:1
PHENOTYPE ANALYSIS OF T LINEAGE DEVELOPMENT IN VITRO EIN: 1140621408A1
PROJ: 02/01/80 - 01/31/83 BUDG: 02/01/82 - 01/31/83 ENC: 03/02/82
AWD 101,349, (DIR 80,000) 0 FUT YRS
```

NOMINATION MEMO - Division of Research Grants

DATE: July 15, 1986

TO: (1) Committee Management Officer, DRG

FROM: Frank James, Ph.D. EXECUTIVE SECRETARYSUBJECT: (1) NOMINATION(S) Medical Research STUDY SECTION/COMMITTEE

*(2) NOTICE OF PENDING NOMINATION(S) TO DRG INITIAL REVIEW GROUP

NAME, DEGREE, TITLE,
DEPARTMENT, SCHOOL, INSTITUTION &
LOCATION

TERMSPECIALTY

BROWN, Carol J., M.D.
Associate Professor
Department of Pediatrics
Medical School
Emory University
Atlanta, GA 30303

7/1/86-6/30/90

Neuropsychology

COLE, John B., Ph.D.
Assistant Professor
Department of Medicine
Medical College of Wisconsin
Milwaukee, WI 53226

7/1/86-6/30/90

Cardiology/Physiology

SMITH, John A., Ph.D.
Associate Professor
Department of Medicine
Medical School
University of Michigan
Ann Arbor, MI 48109

Immediately
to
6/30/89

Pediatric cardiology,
hypertension

REPLACEMENT(S) FOR: Retiring members: Frank Lowe, William Smithy
Resignation: Elbert Maxwell

ATTACHMENTS: CVs and publications for all candidates

FIGURE 7a

REQUEST FOR APPROVAL OF NOMINEE FOR
NIH PUBLIC ADVISORY COMMITTEE
Funded by Scientific Review and Evaluation Awards

REGULAR MEMBER

Committee: Epidemiology & Disease Control

Proposed Term: 7/1/85 - 6/30/89

Study Section (Subcommittee I) _____

Current Term: _____

Nominee: MELTON, Lee Joseph M.D.
(last, first, middle, prof. degrees)

☐ Initial Designation ☐ Redesignation

Position: Associate Professor of Epidemiology

☒ Regular Member ☐ Extension

Address: _____

☐ Chair

Home Address

Place of Birth: Pensacola, Florida

SEE MOST RECENT VERSION.

Date of Birth: 5/17/44

Sponsoring Member: Raymond Neutra

Termination Date: 6/30/85

Special Qualifications of Nominee:

Dr. Melton is an expert in epidemiology of osteoporosis and fractures; diabetes; breast cancer; and endocrine disorders.

Current and Previous HHS Committee Membership and Terms:

SIGNATURES

Date _____ Director, NIH

G OF WAIVER REQUESTS

| <u>occurrences</u> | <u>Approvals</u> | <u>Authority/Policy</u> |
|---|----------------------|--------------------------|
| - | Deputy Director, NIH | NIH policy |
| | Deputy Director, NIH | NIH policy |
| Dep. Dir., NIH/DC | Director, SAC | Department regulation |
| | Director, SAC | Department policy |
| " | " | " |
| " | " | " |
| Excessive service (8 years or more in the last 12 years) | " | " |
| DRG ONLY | | |
| Nominating a candidate from the same institution as a retiring member | Section Chief, DRG | DRG policy |
| More than one Federal member | " | " |

*Membership exceeding 15% from Massachusetts, New York, California and Texas.

DRG/CMO

REQUEST FOR APPROVAL OF NOMINEE FOR
 NIH PUBLIC ADVISORY COMMITTEE
 Funded by Scientific Review and Evaluation Awards

REGULAR MEMBER

Committee: Epidemiology & Disease ControlProposed Term: 7/1/85 - 6/30/89

Study Section (Subcommittee I)

Current Term: _____

 Nominee: MELTON, Lee Joseph M.D.
 (last, first, middle, prof. degrees)

☐ Initial
 Designation

☐ Redesignation
Title: Associate Professor of Epidemiology
☒ Regular Member

☐ Extension

Address:

☐ Chair

Home Address

Place of Birth: Pensacola, Florida

SEE MOST RECENT VERSION.

Date of Birth: 5/17/44Sponsoring Member: Raymond NeutraTermination Date: 6/30/85

Special Qualifications of Nominee:

Dr. Melton is an expert in epidemiology of osteoporosis and fractures; diabetes;
 breast cancer; and endocrine disorders.

Current and Previous HHS Committee Membership and Terms:

SIGNATURES

 Date Director, BID

 Date Committee Management
 Officer, NIH

 Date Director, NIH

FIGURE 8

ROUTING OF WAIVER REQUESTS

| Type of Waiver | Concurrences | | Approvals | | Authority/Policy |
|---|------------------------|---|----------------------|---|-----------------------|
| Lack of a female and/or a minority | - | | Deputy Director, NIH | | NIH policy |
| Excessive membership from a single State* | | | Deputy Director, NIH | | NIH policy |
| Lack of a year's lapse between service on two committees* | Dep. Dir., NIH/DCHE | | Director, SAC | | Department regulation |
| Service on two committees concurrently | " | " | Director, SAC | | Department policy |
| Two members from the same institution | " | " | " | " | " |
| Unbroken service exceeding 4 years | " | " | " | " | " |
| Excessive service (8 years or more in the last 12 years) | " | " | " | " | " |
| <u>DRG ONLY</u> | | | | | |
| Nominating a candidate from the same institution as a retiring member | | | Section Chief, DRG | | DRG policy |
| More than one Federal member | | | " | " | " |

*Membership exceeding 15% from Massachusetts, New York, California and Texas.

DRG/CMO

FIGURE 8 (cont.)
IDENTIFICATION OF RACE AND
NATIONAL ORIGIN CATEGORIES

- I/A American Indian or Alaskan Native: A person having origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition.
- A Asian or Pacific Islander: A person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, Japan, Korea, the Philippine Islands and Samoa.
- B Black, not of Hispanic Origin: A person having origins in any of the black racial groups of Africa. Does not include persons of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish cultures or origins (see Hispanic).
- H Hispanic: A person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish cultures or origins. This includes Spain. Does not include persons of Portuguese culture or origin.
- W White, not of Hispanic Origin: -A person having origins in any of the original peoples of Europe, North Africa, or the Middle East. Does not include persons of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish cultures or origins (see Hispanic). Also includes persons not included in other categories.

Source: Federal Personnel Manual
No. 298-10
- SF 181

CMO/NIH
5/20/87

PROFESSIONAL AREA BREAKDOWN

Bio-organic & Natural Products Chemistry Study Section

FIGURE 9

Authorized Public Positions - 18

| Name | Term Ending | Expertise | Geog. Dist. | Minority/Female |
|--------------------------|----------------|---|----------------|-----------------|
| Bartlett | 6/30/87 | Nucleosides & phosphorus chemistry, enzyme mechanisms, organic synthesis | CA | |
| Kozarich | 6/30/87 | Enzyme inhibitors and enzyme mechanisms, biochemistry of modified nucleosides | MD | |
| Rodriguez | 6/30/87 | Natural products isolation & phytochemistry | CA | X |
| Stubbe | 6/30/87 | Enzyme mechanisms & mechanism based inhibitors, nucleoside/nucleotide biochemistry | WI | X |
| Erickson | 6/30/88 | Peptide synthesis & sequencing, design of biologically active peptides & immunochemistry | NY | |
| Hurley | 6/30/88 | Biosynthesis, drug-DNA interactions, mechanism of antitumor agents | TX | |
| Otter | 6/30/88 | Chemistry of nucleosides, nucleotides & polynucleotides, design of antitumor/antiviral agents | NY | |
| Roth | 6/30/88 | Medicinal chemistry, drug design, receptor studies, enzyme inhibitor studies | NC | X |
| Anderson | 6/30/89 | Medicinal chemistry; design, synthesis & testing of CNS-active compounds | PA | |
| Berchtold | 6/30/89 | Polyaromatic hydrocarbon carcinogenesis, organic synthesis, biosynthesis | MA | |
| Hruby | 6/30/89 | Synthesis, structure, and function of peptides, particularly hormones | AZ | |
| Shimizu | 6/30/89 | Natural products chemistry; isolation & structure elucidation of plant & marine natural products | RI | |
| Townsend | 6/30/89 | Biosynthesis, spectroscopy, & organic synthesis | MD | |
| Chang | 6/30/90 | Spectroscopic studies of chemical carcinogenesis, biosynthesis, & natural products chemistry | IN | X |
| Rebek, Jr. | 6/30/90 | Enzyme mimics, enzyme modelling, & host-guest chemistry | PA | |
| Rivier | 6/30/90 | Design, synthesis, and biological testing of peptides | CA | |
| <u>PROPOSED NOMINEES</u> | | | | |
| Agarwal | 6/30/90 | Polynucleotide chemistry, design, synthesis, reactivity and binding characteristics | IL | X |
| Bergstrom | 6/30/91 | Design and synthesis of nucleosides, nucleotides, and polynucleotides as antiviral or antitumor agents | ND | |
| Colman | 6/30/91 | Small molecule enzyme interactions, inhibitor studies, affinity labelling studies and enzyme mechanisms | DE | |
| Fenical | 6/30/91 | Marine natural products isolation and structure elucidation, chemical ecology | CA | |
| Katzenellenbogen | 6/30/91 | Enzyme inhibitor design and testing, synthetic organic chemistry, radiopharmaceuticals | IL | |
| Silverman | 6/30/91 | Design, synthesis, and testing of enzyme inhibitors, mechanism of action enzyme models drug design | IL | |



FIGURE 10
LETTER OF INVITATION
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20205
Building Westwood
Room : 450
(301) 496- 7211

February 13, 1986

Richard R. Streiff, M.D.
Medical Service
Veterans Administration Hospital
Gainesville, FL 32602

Dear Dr. Streiff:

On behalf of the Director, National Institutes of Health (NIH), it is my pleasure to invite you to serve as a member of the Nutrition Study Section, Division of Research Grants, for the term beginning July 1, 1986, and ending June 30, 1990. As I am sure you know, membership on a study section represents a major commitment of professional time and energy as well as a unique opportunity to contribute to the national biomedical research effort. Study sections review grant applications submitted to the NIH, make recommendations on these applications to the appropriate NIH national advisory council or board, and survey the status of research in their fields of science. These functions are of great value to medical and allied research in this country.

You have been nominated because of your demonstrated competence and achievement in your scientific discipline, evidenced by the quality of your research accomplishments, publications in scientific journals, and other significant scientific achievements and honors. Service on a study section requires mature judgment and objectivity as well as the ability to work effectively in a group, qualities we believe you will bring to this important task.

Study sections usually meet three times a year in Bethesda, Maryland, for one or more days each time. Members receive \$100 per day for time spent at meetings or on site visits. In addition, members are allowed travel expenses and per diem while serving away from their places of residence. The per diem rate is determined by the location at which service is performed; the general rate is up to \$75 per day for actual expenses incurred. For Federal government employees, the \$100 per day honorarium is not allowable.

Dr. Nathan Watzman, Acting Executive Secretary
Section, before you decide whether or not to
(301-496-7178). He will elaborate on the nature
you would be expected to make, the satisfactions you
the study section in detail, and answer any
have about compensation, work load, procedures and

Page 2 - Dr. Streiff

Enclosed is an Administrative Fact Sheet which provides general details of membership and describes the forms you are asked to complete. A self-addressed envelope is also enclosed for your convenience in returning the forms.

We hope you will accept this invitation; we would welcome your contributions to the review process.

Sincerely yours,

Jerome G. Green, M.D.
Director
Division of Research Grants

Enclosures

cc: Dr. Watzman



CONFIRMATION LETTER

FIGURE 11
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

February 14, 1986

National Institutes of Health
Bethesda, Maryland 20201
Building : Westwood
Room : 453
(301) 496- 7534Pak Hoo Chan, Ph.D.
Department of Neurology
University of California
San Francisco, CA 94143

Dear Dr. Chan:

Thank you for completing and returning the forms indicating your interest in serving on the Neurology A Study Section of the Division of Research Grants. We are delighted that you have agreed to participate in the important work of the National Institutes of Health (NIH). Dr. Katherine Woodbury, the Executive Secretary of that study section, will provide you with additional information concerning your service. For your convenience, we are enclosing a copy of a roster of study section members.

Form HHS-474, "Confidential Statement of Employment and Financial Interest," which you provided, has been reviewed and no actual or apparent conflict of interest was identified. It would prevent you from serving on the Neurology A Study Section. Regular matters might arise, however, at study section visits, that could present a conflict of interest. It is primarily your responsibility to evaluate actual or potential conflicts of interest situations. Please read carefully the Review Regulations sent to you previously. Whenever your participation in deliberations on a project, program, product, or other particular matter would or might appear to constitute a conflict of interest or create the appearance of one, it is incumbent upon you to inform the Executive Secretary.

The Committee Management Office is responsible for ensuring that regulations concerning financial disclosures are followed, for providing information about advisory committees, and for checking that the biographical and other information you provide the NIH is complete. If you have any questions about these issues, please call me collect on (301) 496-7534. However, if you need additional information about review procedures or related matters, please call Dr. Woodbury collect at (301) 496-7095.

Sincerely yours,

Mary H. Shook
Committee Management Officer
Division of Research Grants

Enclosure

cc: Dr. Woodbury

REQUEST FOR APPROVAL OF NOMINEE FOR
NIH PUBLIC ADVISORY COMMITTEE
Funded by Scientific Review and Evaluation Awards

Committee: Physiological ChemistryProposed Term: 7/1/85 - 6/30/86Current Term: 9/14/82 - 6/30/86
 Nominee: DONELSON, John E., Ph.D.
 (last, first, middle, prof. degrees)

☐ Initial Designation
 ☐ Redesignation
Title: Professor
☐ Regular Member
 ☐ Extension

Address:

☒ Chair

Home Address

Place of Birth: Ogden, IowaBirth: 5/23/43Retiring Member: Don Carlson

SEE MOST RECENT VERSION.

Termination Date: 6/30/85

Special Qualifications of Nominee:

Dr. Donelson is an expert in gene expression and cloning. He has been a conscientious member of the Physiological Chemistry Study Section, showing himself to be knowledgeable, judicious, and an interactive member of the consensus process.

Current and Previous HHS Committee Membership and Terms:

SIGNATURESDate Director, BIDDate Committee Management
Officer, NIHDate Director, NIH

NIH/CMO 08/01/84

NIH Test Form 8/84

FIGURE 13 COMPETENCY ROSTER

ORTHOPEDICS AND MUSCULOSKELETAL STUDY SECTION

| MEMBERS | AREA OF COMPETENCE |
|--|--|
| <u>CHAIRPERSON</u> | |
| Lane, Joseph M., M.D. (86) Professor Department of Orthopedic Surgery The Hospital for Special Surgery New York, NY 10021 | Orthopedic surgery; biochemistry of bone and cartilage; metabolic bone diseases; bone tumors; fracture biology |
| Andriacchi, Thomas, P., Ph.D. (88) Associate Professor Department of Orthopedic Surgery Rush-Presbyterian-St. Luke's Med. Ctr. Chicago, IL 60612 | Biomedical engineering; biomechanics of joints and spine; gait analysis |
| Canalis, Ernesto, M.D. (88) Associate Professor Department of Medicine Univ. of Connecticut Medical Center-- Farmington, CT 06510 | Bone metabolism; endocrinology; collagen biochemistry; cell e; and growth factors |
| Teitelbaum, Steven L., M.D. (87) Professor, Dept. of Pathology Washington University The Jewish Hospital of St. Louis St. Louis, MO 63110 | Internal medicine; bone biochemistry and metabolism; bone pathology |
| Appointment Pending (89) | Bone metabolism and minerals |
| Appointment Pending (89) | Mechanical engineering; biomechanics; theoretical & applied mechanics; finite element analysis |

SEE MOST RECENT VERSION.

Chapter III

STUDY SECTION MEETING ARRANGEMENTS

Future study section meeting dates are decided on during a study section meeting. After the meeting, the Grants Assistant and Executive Secretary begin to make arrangements to secure adequate meeting space. The procedures and guidelines for these arrangements follow.

A. DATES

Study section meetings, which usually last several days, are held three times a year--in June, in October to November, and in February to March. Meeting dates are usually chosen by the study section members at least two meetings in advance. Meeting schedule listings for each meeting period (dates, times, and locations) are prepared by the Conference Coordinator, Office Services Section, Administrative Branch, Room 455, Westwood Building, and are available through an NIH computer listing on TSO. (Instructions are found in the User Resource Office.)

B. LOCATIONS

Study section meetings should be held in conference rooms in NIH buildings if available. (See Table 2 for such conference rooms, which are free.) Hotels close to the NIH campus should be used for overnight accommodations. If space is unavailable on the NIH campus, meeting rooms in hotels in Bethesda or elsewhere in the Washington metropolitan area may be used, preferably close to the NIH Campus. With prior approval, meeting rooms in hotels in other cities may be utilized.

NIH conference rooms are reserved through a central coordinator. (See Section C-1.) Reservations for Uniformed Services University conference rooms are made through Dr. Redington (295-3303), and for the Lister Hill Center conference rooms through Ms. Linda Sheets (496-5389). To reserve a DHHS conference room in the Washington, D.C. facilities, call 245-7621.

When meetings are held in the C Wing of Building 31, the Conference Services Section (496-6161) can provide phone and reception services, arrange for coffee breaks, and supply certain materials. No services are available on Saturdays and Sundays in Bldg. 31, and no such services are available for other NIH building conference rooms.

Parking arrangements on the NIH reservation should be requested a month before the meeting by calling the Conference Services Section for parking permits for study section members. Space will probably be assigned in the 31C lot of Building 31. After parking permits are received, they should be sent to the appropriate individuals. Staff may park in areas that are not designated for visitors or carpools. An NIH map indicating these parking areas is on the back cover of the NIH Telephone Directory.

C. CONFERENCE ROOM REQUESTS

1. Requests for NIH Conference Rooms

As soon as meeting dates are firm, the Grants Assistant should call the NIH Conference Space Coordinator, Dot Mudrick (496-6260) to request a meeting room. Be sure to identify the organization as a DRG study section, because the priority time for study sections will be maintained. If space is available, the Grants Assistant must fill out Form NIH 827, Request for Conference Room (Figure 14). This form is then submitted to Conference Services, Building 31, Room 6C17. A copy is kept for study section records.

2. Requests for Non-NIH Conference Rooms in the Washington Metropolitan Area

The Grants Assistant requests approval for an off-reservation meeting room by sending a memorandum, in duplicate, to the Deputy Chief for Review, RRB, through the Conference Coordinator, DRG, Westwood Building, Room 455. The brief memorandum should include the date, the proposed hotel, and the charge for guest rooms and conference rooms. The Grants Assistant then completes Part 2 of Form NIH 2011 Notification of Extramural Meeting (Figure 15), files the last copy of the completed form, and forwards the other copies, along with the memorandum, to the Conference Coordinator, DRG.

This request must be submitted according to the Scheduling for Submitting Form 2011 (Figure 16), but may be requested a year in advance if the dates are firm. Confirmation on future requests may be delayed somewhat by the NIH, since reservations for the current round of meetings are handled first. As always, the unavailability of NIH conference space must be verified before approval is given for off-campus meetings.

3. Requests for Conference Rooms at Out-of-Town Sites

Requests for conference rooms at out-of-town meetings must be submitted well in advance of the meeting date. (Currently, a lead time of about 9 months is required.) Deadlines for submitting requests are announced periodically by memoranda. Out-of-town meetings must be approved by a special RRB committee and are dependent on available funds. The request should be made by sending an original and nine copies of a memorandum through the appropriate Section Chief to the Deputy Chief for Review, RRB. In addition to the specific justifications, the memorandum should include a list of the members of the study section and a comparison of the cost of the proposed out-of-town meeting with the cost at the NIH (Figure 17 and 18). During an out-of-town meeting the Grants Assistant is expected to be present to perform the same tasks as for a meeting held at the NIH. Regular per diem and travel expenses are provided.

The principal justification for holding an out-of-town study section meeting is that it will be held in conjunction with a national scientific meeting attended by a majority of study section members in connection with a study section sponsored workshop for which there is a valid reason for having an out-of-town location.

As soon as possible after approval has been received and an out-of-town conference room reserved, the Grants Assistant completes Part 2 of FOA-101 NIH 2011 (Figure 15), files the last copy of the completed form, and forwards the other copies to the Conference Coordinator, DRG. The Grants Assistant includes the name and location of the hotel, the name and number of the meeting room, and a telephone number at which persons attending the meeting can be reached.

Five copies of the agenda and five copies of the roster should be sent to the Conference Services, Building 31, Room 6C17, no matter where the meeting is held. If meeting dates or location change prior to the meeting, the Conference Coordinator must be notified by memo as soon as possible.

4. Requests for Telephone Conference Calls

Telephone conference calls can be arranged through the NIH operator or through a conference call organization such as American Teleconferencing Services, Ltd., (913) 661-0700. Upon request, the company will send all the information needed to set up a telephone conference call. For each telephone conference call, a memorandum (Figure 19) must be completed by the Grants Assistant and approved by the appropriate Section Chief, who forwards it to the Budget Office, DRG.

In addition to the normal correspondence and review materials, the Grants Assistant should send the Consultant Claim Form (Figure 20) to the Reviewers. Reviewers are entitled to receive a \$100 consultant fee for participating in the conference call review. This fee will be increased in the near future to \$150.

5. Rooming Lists for Hotels

No later than 2 weeks prior to a study section meeting, the Grants Assistant should send to the hotel a list of members and special reviewers for whom rooms have been reserved. Prior to this action, each member or special reviewer should be notified of the reservation (hotel name, address, and telephone number) and the hotel's late arrival policy. In addition, they should be advised that they are responsible for guaranteeing their rooms and making any change of reservations, such as changing from a single room to a double room or canceling.

D. CONFERENCE ROOM ARRANGEMENTS FOR MEETING HELD AWAY FROM NIH

For meetings held away from NIH, the Grants Assistant, with the concurrence of the Executive Secretary, makes the arrangements for a suitable conference room in a selected hotel. In most cases, the Grants Assistant signs a contract with that hotel. Permission to use such rooms must

requested by memorandum to the Deputy Chief for Review, RRB, in which the place and date of the proposed meeting and the cost of the conference rooms are listed. For unfamiliar meeting rooms, advance scrutiny is recommended to ensure pleasant surroundings, good ventilation, adequate space, proper lighting, and the absence of intrusive noise. Since most hotels charge for conference rooms, the most reasonable room of suitable size should be chosen. Occasionally a hotel will provide a conference room free of charge with the guarantee of a block of guest rooms. The conference room should have tables large enough for the expected number of study section members, the Executive Secretary, and the Grants Assistant, and should have sufficient additional seating for observers.

E. STUDY SECTION CONFERENCES AND WORKSHOPS

Study section conferences, workshops, or subcommittee meetings must receive prior approval by a special RRB committee, and must be held in conjunction with a study section or professional society meeting. A request is made by sending an original and nine copies of a memorandum through the appropriate Section Chief to the Deputy Chief for Review, RRB. When possible, an Executive Secretary should notify the appropriate Section Chief about a workshop in its early planning stage and prior to the submission of any formal request (Figure 21).

The requesting memorandum should include the following information:

- Specific objectives of the activity;
- Proposed location and dates;
- Plans for publication of the results; and
- Budget breakdown (exclusive of the study section meeting), including charges to DRG operating funds, such as travel and per diem for Government employees; charges to the Scientific Review and Evaluation Award, including names and location of participating non-study section consultants; consultant costs; incidental charges, such as rental of conference space and equipment; and, when indicated, a cost comparison between an out-of-town location and Bethesda. (See Figures 18 and 22.)

Institutes with programmatic interests in a workshop should be informed of preliminary plans to determine if joint sponsorship and cost sharing are feasible. In certain circumstances, a study section can support a conference jointly with another organization or study section, but permission must first be obtained from the appropriate Section Chief.

Workshop requests are reviewed according to the importance of the topic to the progress of science and the mission of the NIH and are judged against available funds and other workshop requests.

Workshops can last no more than 2 days and involve only members of the sponsoring study section, no more than 10 speakers or Chairpersons who are not members of the sponsoring study section, and relevant NIH extramural staff. Consultant fees, travel, and other standard expenses are allowed

for non-Federal employees who participate as chairpersons or speakers in such workshops. Non-Federal employees who attend but do not participate in these workshops may receive travel and per diem reimbursement but not consultant fees.

After the planning is approved, the Executive Secretary is responsible for keeping adequate records about workshops and conferences. A short report on the workshop or conference should be submitted to the Office of the Assistant Chief for Special Projects, DRG, as soon as the arrangements for the event have been confirmed. The report is entered into the NIH Conference Module file, formerly published as the Schedule of NIH Conferences. The format for the report is provided in the Pre-Workshop/Conference Report (Figure 23). A summary of the outcome of the conference is no longer required. If a formal publication results, a copy is to be given to the Section Chief and the Chief, RRB. Copies of significant documents relating to workshops or conferences, such as agendas, programs, special subcommittee reports, recommendations to specific organizations, and books published under study section auspices, should be retained in study section files. The office of the Chief, RRB, DRG, should be kept fully informed about all such activities.

Since dates of conferences, meetings, workshops, and subcommittee meetings are published in the Federal Register, the Grants Assistant should report any changes of place or date to the CMO as soon as possible.

TABLE 2

NO CHARGE CONFERENCE ROOMS

| <u>Room Number</u> | <u>Capacity</u> | <u>Location</u> | <u>Phone Number for Services</u> |
|--------------------|-----------------|---|----------------------------------|
| 2 | 36 | Building 31, A Wing, 1st Floor | 496-6161 |
| 3 | 55 | " " " | " |
| 4 | 75 | " " " | " |
| 6 | 130 | Building 31, C Wing, 6th Floor | " |
| 7 | 52 | " " " | " |
| 8 | 52 | " " " | " |
| 9 | 52 | " " " | " |
| 10 | 120 | " " " | " |
| Wilson Hall | 150 | Building 1 | " |
| B119 | 30 | Federal Building | " |
| A | 56 | Landow Building, 1st Floor | " |
| B | 12 | " " | " |
| C | 12 | " " | " |
| E | 36 | " " | " |
| Med. Board Rm. | 35 | Clinical Center | 496-3475 |
| A-2011 | 20 | Uniformed Services University (multidiscipline labs) | 295-3301 |
| A-2015 | 20 | " " " | " |
| A-2053 | 30 | " " " | " |
| A-2054 | 35 | " " " | " |
| Lecture Rm. A | 54 | " " " | " |
| Lecture Rm. B | 58 | " " " | " |
| Lecture Rm. C | 120 | " " " | " |
| N-MAC Classroom | 60 | Lister Hill Center | 496-5389 |

*Uniformed Services University facilities should not be used if an application from that institution is to be reviewed.

FIGURE 14

| | | | |
|--|--|--|--------------------------------|
| ADMINISTRATIVE SERVICES BRANCH TECHNICAL SERVICES 496-6260 FOR CONFERENCE ROOM | | Complete this form and send the first four copies to: Reservation Clerk, Building 31, Room 6C17. Please include a list of conference participants. | |
| OFFICIAL RESPONSIBLE FOR CONFERENCE | | PHONE NO | DATE OF REQUEST |
| OFFICE CONTACT | | PHONE NO | BLDG ROOM |
| PURPOSE OF CONFERENCE | | BID | |
| | | NO PERSONS ATTENDING (Approx) | |
| CONFERENCE ROOM NO | | BUILDING NO. | CAN NO |
| DATE OF CONFERENCE | CHECK DAY(S) OF THE WEEK <input type="checkbox"/> MON <input type="checkbox"/> TUES <input type="checkbox"/> WED <input type="checkbox"/> THURS <input type="checkbox"/> FRI <input type="checkbox"/> SAT <input type="checkbox"/> SUN | STARTING TIME ON THE FIRST DAY | ENDING TIME ON THE LAST DAY |
| SUPPLIES NEEDED Pencils & pencils around conference table Pencils & pencils on side table Name plate holders (blocks) Level & block Telephone for desk outside conference room Name tag racks Door stand for council sign "Closed session" sign Registration sheets Hardboard boxes for trash & returning material | | QTY. AUDIO VISUAL SERVICES REQUIRED <input type="checkbox"/> Tape record meeting <input type="checkbox"/> Sound system required <input type="checkbox"/> Electric pointer <input type="checkbox"/> 2 x 2 (Carousel) slide projector (35 mm) <input type="checkbox"/> CCTV playback <input type="checkbox"/> CCTV - overflow (explain below) <input type="checkbox"/> Videotaping (for information, call 496-4700) <input type="checkbox"/> Transparency - overhead projector <input type="checkbox"/> 16 mm projector | |
| Work times: AM _____ PM _____ (Permits call the Parking Office on 496-6851) | | SIGNATURE OF CONFERENCE SPONSOR | |
| INSTRUCTIONS | | | |
| LOCATION OF CONFERENCE ROOM Is the telephone reservations made for the above conference room. | | SIGNATURE OF PERSON CONFIRMING RESERVATION | DATE |

FIGURE 15

Notification of Extramural Meeting

| NOTIFICATION OF EXTRAMURAL MEETING | | | |
|---|-------------------------------|--------------------------|-----------|
| ATTENTION: Submit 3 copies for each meeting to Scientific Review Branch, NIH. For conference rooms or reservations, confirmation card will be returned to requesting office. | | | |
| TO | SCIENTIFIC REVIEW BRANCH, NIH | BUILDING AND ROOM NUMBER | DATE |
| FROM | NAME OF REQUESTER | BUILDING AND ROOM NUMBER | TELEPHONE |

PART 1A. REQUEST FOR CONFERENCE ROOM - ON RESERVATION

| | | | |
|---|------------------------------------|--|---------------|
| INSTITUTE SYMBOL | NAME OF STUDY SECTION OR COMMITTEE | | |
| DATES OF MEETING | | DAYS OF WEEK | STARTING TIME |
| CONFERENCE ROOM PREFERENCE FIRST CHOICE | | CONFERENCE ROOM PREFERENCE SECOND CHOICE | |
| NUMBER TO BE SEATED AT CONFERENCE TABLE | | NUMBER OF OBSERVERS EXPECTED AT ANY ONE TIME | |
| REMARKS | | | |

PART 1B. CONFIRMATION OF CONFERENCE ROOM - ON RESERVATION

| | | |
|--|---------------|------|
| CONFERENCE ROOM _____ IN BUILDING _____ HAS BEEN RESERVED FOR YOU. | | |
| SIGNATURE OF PERSON CONFIRMING RESERVATION | TELEPHONE NO. | DATE |

PART 2. NOTICE OF MEETING - OFF RESERVATION

| | | | |
|------------------|------------------------------------|----------------|---------------|
| INSTITUTE SYMBOL | NAME OF STUDY SECTION OR COMMITTEE | | |
| DATES OF MEETING | | DAYS OF WEEK | STARTING TIME |
| PLACE OF MEETING | | CITY AND STATE | |
| REMARKS | | | |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date November 6, 1986
 from Deputy Chief for Review, RRB, DRG

SEE MOST RECENT VERSION

Subject Study Section Meeting Dates

To All Executive Secretaries and Grants Technical Assistants, RRB, DRG

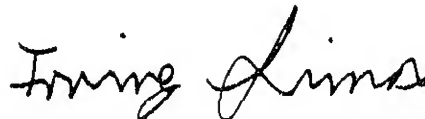
Notices of Federal Advisory Committee meetings must now be published in The Federal Register 60 days prior to the date of the particular meeting. Since our study sections meet over a four-week period each round, Mary Shook, DRG, CMO, must have the dates in sufficient time to submit all the dates at one time. Therefore, each office must meet the following schedules for submission of form 2011 (Notification of Extramural Meeting) to Judy Wright, Administrative Branch, Room 455.

| <u>Meeting</u> | <u>Final Submission Date</u> |
|------------------|------------------------------|
| February/March | November 1 |
| June | February 20 |
| October/November | June 15 |

For Manpower Study Sections:

| | |
|-----------|------------|
| January | October 1 |
| May | February 1 |
| September | June 1 |

Thank you for your cooperation.



Irving Simos, Ph.D.

COST COMPARISON FOR OUT-OF-TOWN MEETING REQUESTS ^{1/}

| (Name of study section) | (Dates of meeting) | | | |
|---|--------------------|--------------|-----------|--------------|
| (Proposed location for meeting) | COSTS | | | |
| | Bethesda | | Proposed | |
| | DRG Funds | SEG 1/ Funds | DRG Funds | SEG 2/ Funds |
| Travel costs: 2/ | | | | |
| (No.) Study Section consultants | | | | |
| (No.) Other consultants | | | | |
| (No.) Staff | | | | |
| Subtotal | | | | |
| Per diem costs: 3/ | | | | |
| (No.) Study Sec. consultants for (no.) days | | | | |
| (No.) Other consultants for (no.) days | | | | |
| (No.) Staff for (no.) days | | | | |
| Subtotal | | | | |
| Other costs (itemize): | | | | |
| <u>Fees for consultants (total amount)</u> | | | | |
| <u>Meeting room (total amount)</u> | | | | |
| | | | | |
| | | | | |
| Subtotal | | | | |
| Total | | | | |
| GRAND TOTAL, DRG and SEG funds | | | | |

If workshop is included in proposal, show cost for Study Section Meeting only:

1/ Please attach Roster of Members.

2/ Use airline guide for travel costs and add per diem

3/ Cost to be paid from Scientific Evaluation (Chairman's) Grant.

OUT-OF-TOWN MEETING/WORKSHOP REQUEST MEMO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date

From: Executive Secretary, Study Section
 Thru: Chief, Review Section, RRB

Subject: Proposed Workshop and Study Section Meeting, February 198

To: Deputy Chief for Review, RRB

Investigation of the role of metals in biologically important molecules has increased at a rapidly changing rate in the last ten years and represents an important interface between inorganic chemistry and biochemistry. In 1975 a workshop was sponsored by NIH and NSF to enhance the interactions between inorganic chemists, many of whom investigated well-defined model compounds of potential biological interest, and biochemists, using as material for investigation more complex compounds derived from living systems. The success of the endeavor can be easily measured by the increased numbers of collaborative approaches between inorganic and biochemists, the broader experimental approaches used by investigators trained in each individual discipline, and finally, the training of new investigators who are clearly inorganic biochemists. The proposed program (enclosed) for the 1984 Gordon Conference, Metals in Biology, typifies the contemporary breadth of research in inorganic biochemistry.

The next logical stage of growth is at the interface of inorganic biochemistry and medicine. Several notable examples already exist, such as the construction and use of $\text{cis}(\text{NH}_3)_2\text{PtCl}_2$ and bleomycin in the treatment of malignancies. (Bleomycin is an antitumor antibiotic whose biological activity is believed to be due, at least in part, to its interactions with and degradation of DNA which is mediated by metal ions and oxygen.) However, the potential is much greater and the time is now appropriate to provide an opportunity for basic scientists to become more aware of the medical implications of their research and for physicians to become more aware of the relevance of research in inorganic biochemistry to their concerns.

Accordingly, a workshop, "Metals in Medicine," is proposed, covering topics NOT covered in the Gordon Conference.

Metals are known to be important in biological conversation to occur about such metals at the interface of biology and medicine, the research in each area needs to be coordinated. Unfortunately, at this time such is not the case. Accordingly, subjects for the proposed workshop should be selected for the efficacy of providing information that both groups expected to participate.

Many of the basic scientists who can benefit from the proposed workshop will attend the Gordon Conference on "Metals in Biology" in Santa Barbara, February 6-10, 1984. Accordingly, it is proposed to schedule the workshop immediately following the Gordon Conference on February 10-11, 1984. The workshop will be advertised in coordination with the Gordon Conference and to physicians and basic scientists in the California area. It is clear that the members of the Study Section would benefit greatly from such an opportunity since the subject of the workshop coincides precisely with the subject of a large fraction of the grants reviewed. Some of the Study Section members will also participate in the Gordon Conference. It therefore would be appropriate to schedule the February Study Section meeting immediately following the proposed workshop. Approximately 50-75 attendees in the proposed workshop can be expected. They will pay their own costs.

The proposed format of the workshop is the presentation of lectures in which each speaker will address the pathology of abnormal metal metabolism and/or the therapeutic use of metal complexes related to inorganic biochemistry. Relevant pathological conditions are exemplified by osteoporosis (calcium), hemochromatosis, and thalassemia (iron), Menkes' and Wilson's Diseases (copper), acrodermatitis enteropathica (zinc), and Alzheimer's Disease (aluminum). Discussion between the participants and a panel formed by the speakers will follow. A lively and informal interchange is anticipated because of the ambience established at the Gordon Conference on the preceding days.

Six speakers, all considered to be authorities in the field, have enthusiastically accepted tentative invitations to participate in the workshop. The speakers and titles of their talks are as follows:

Ph.D., Madison, WI: Calcium, Vitamin D, and Bone Disease

M.D., New York, NY: Chemical Pathology of Iron Deficiency and Iron Overload

Ph.D., Toronto, Ontario: Copper Handling in Human Disease

M.D., Cambridge, MA: Human Biology, Biochemistry, and Pathology of Zinc

M.D., Lexington, KY: Aluminum and Other Trace Metals in the Brain and in Alzheimer's Disease

Ph.D., Baltimore, MD: Cadmium Toxicity in Humans

Ph.D., Raleigh, NC, a member of the Study Section has agreed to chair the workshop. Other members of the Study Section have agreed to participate as discussants. Three current members of the Study Section are included in the proposed program for the Gordon Conference, as are at least four former Study Section members, which emphasizes the relevance of the Gordon Conference and the workshop to the interests of the Study Section. Furthermore, leading scientists from all over the world attending the Gordon Conference would have the

opportunity to participate in the workshop and could present significant new information in the area of metals in medicine.

The estimated cost of holding the workshop and February 1984 Study Section meeting in Santa Barbara is virtually the same as having both activities in Bethesda. A cost comparison is attached. The total expense to the Chairman's Grant is estimated to be approximately \$19,089 for both. The AM Institute has expressed an interest to participate in the workshop. Approval of this proposal is respectfully requested.

Proceedings of the workshop will be published providing funds are available

Enclosures



FIGURE 19

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date _____

From Executive Secretary,
Study Section, DRG

Subject Reimbursement for Telephone Conference Call Review

THRU Chief, Review Section

To Budget Office, DRG

The roster attached identifies the telephone conference.

Date of Conference Call Review: _____

Principal Investigator(s): _____

Application Number(s): _____

Number of consultants participating: _____

Number of consultants participating by phone: _____

Origin of phone call: _____

Justification for conference call review:

ATTACHMENT

Submit in TRIPLICATE Please read carefully, including information on reverse

| | | | | | |
|--|------|---|--|-------------------------------|-------|
| Department of Health and Human Services Public Health Service, National Institutes of Health | | DATE | | | |
| Claim for Reimbursement of Travel Cost, Per Diem, and Consultant Fee | | | | | |
| NAME OF CHAIRMAN | | STUDY SECTION, REVIEW GROUP, OR COMMITTEE | | | |
| PLACES AND DATES OF ASSIGNMENT | | | | | |
| Note: In cases of combined personal and official business during the same trip, show departure and return time that could have been followed for the sole purpose of this assignment. Take this into account in itemizing expenses below. | | | | | |
| LEFT (City, date, hour) | | DATE OF MEETING(S) OR SITE VISIT(S) | | | |
| RETURNED (City, date, hour) | | | | | |
|) Cost of transportation (receipts required). If mixed mode of travel, indirect routing or stopovers for personal reasons are involved, claim only cost of usual direct-route round trip fare. If travel is by privately owned plane, 45¢ an air mile is allowed; or by private auto, _____ ¢ a mile (not to exceed cost by common carrier) will be allowed. | | | | | |
| Odometer Readings | | Amount of Advance (when applicable): \$ | | | |
|) Taxi or limousine used for official business, including up to 15% for tips. (Receipt not required.) | | \$ | | | |
|) Other (Examples - Road and bridge tolls, parking, telegram and telephone calls for official business, conference room rentals.) Receipts required only on items costing \$25 or more. Flight or other travel insurance is considered a personal expense and is not reimbursable. | | \$ | | | |
| Identify claims: | | \$ | | | |
|) TOTAL TRAVEL EXPENSES | | \$ | | | |
|) Lodging. Itemize each day's lodging costs (including tax). This information is needed to determine the appropriate per diem allowance under the Standard Conus system, and the Per Diem Locality Rate method. (See reverse.) | | REMARKS: If unusual circumstances regarding an assignment affect your claim, explain here or on an attached page. | | | |
| DAY | DATE | | LODGING | MEALS AND INCIDENTAL EXPENSES | TOTAL |
| | | | \$ | \$ | \$ |
| | | | | | |
| | | | | | |
| | | | | | |
| STATEMENT OF PERSONAL SERVICE | | | | | |
| I certify that the above itemization reflects costs incurred for official business and that I provided consultant services in connection with this assignment on the dates indicated | | | | | |
| HOME ADDRESS | | | ADDRESS (where check is to be mailed if other than home) | | |
| SOCIAL SECURITY NO. (See Privacy Act statement on reverse) | | NAME (typed) | | SIGNATURE OF CONSULTANT | |
| THIS SECTION FOR NIH USE ONLY | | | | | |
| I certify that the above Consultant is entitled to a consultant fee for _____ days at \$100 per day. | | | \$ | | |
| Signature of Executive Secretary | | | | | |
| Standard Conus \$ | | | /Per Diem Locality Rate \$ | | |
| Travel (from Item D, above) | | | \$ | | |
| ADVANCE DEDUCTED (when applicable) | | | \$ | | |
| TOTAL TO BE PAID | | | \$ | | |
| Audited by | | Approved by | | <input type="checkbox"/> Code | |

General Instructions

1. Complete the form through the "Statement of Personal Services" section. Attach the receipts to the original and submit this form in triplicate to the NIH office that requested your services for this assignment. Incomplete forms will be returned.
2. Only a consultant fee can be offered in "local travel" situations. Local travel is defined as that within one's home city, when the one-way distance to duty point is 75 miles or less.
3. Claims for long-distance official business telephone charges should include the name of the person called, as well as location.
4. Cash purchase of transportation will be necessary if travel is by air. Economy flights should be used.
5. If you provide services for some other organization during this same trip, the travel cost must be pro-rated between the two sponsors in whatever manner you determine is fair. In no case will more than usual round trip coach fare be reimbursed.
6. Reimbursement for travel, per diem, and consultant fees will be by a single check. The fee portion should be considered as income and so declared in your personal tax return. Income tax will not be withheld at the time of payment.

Computing Per Diem

1. Explanation of Per Diem Locality Rate
 - a. The maximum rates range from \$55-\$126 depending upon the area.
 - b. Meals and incidental expenses will be flat rate of either \$25 or \$33 depending upon the area. Day of departure and return up to one half of daily allowance.
 - c. Meals and incidental expenses will *not* be itemized.
2. Explanation of Standard Conus Rate
 - a. The rate not to exceed \$50. Meals and incidental expenses will *not* be itemized.
 - b. *Lodgings:* Up to the maximum allowance of \$25.
 - c. *Meals and incidental expenses:* Up to the maximum allowance of \$25. Day of departure and return up to one half of daily allowance.
3. You must attach lodging and parking receipt to your voucher.
4. If your lodging, meals, and incidental expenses for a day are less than the prescribed daily maximum, you will be reimbursed only the amount of your expenses for that day. If your lodging, meals, and incidental expenses for the day are more than the prescribed daily maximum, you will be reimbursed only the amount of the prescribed daily maximum for that day.

If you travel to separate locations during a single trip and some locations are "Per Diem Locality Rate" areas and some are "Standard Conus" localities, your reimbursement will be based on a combination of rates.

Privacy Act Information

We will retain your Social Security Number in a file associated with your name and address. This file is used in the accounting system to produce and mail checks in settlement of our indebtedness to you and to report payments to the Internal Revenue Service. The furnishing of your Social Security Number is required with the statements and other documents which must be filed with the Internal Revenue Service under Federal Tax Regulations (Title 26, Code of Federal Regulations, Section 31.6109). NIH is required to annually furnish you with Form 1099, "Statement for Recipients of Miscellaneous Income," required by Federal Tax Regulations (Title 26, Code of Federal Regulations, Section 1.6041). The use of Social Security Numbers is mandatory for Federal accounts relating to individual persons under Executive Order No. 9397, November 22, 1943. In this instance, failure to provide your Social Security Number will result in delay of payment of monies due and hinder the processing of tax data. (This information is provided to you in accordance with the Privacy Act of 1974).

FIGURE 21

POLICY ON STUDY SECTION WORKSHOPS

Background

DRG encourages study sections to hold workshops on scientific topics in areas related to their review guidelines and the expertise of the members. Such workshops are useful in assessing the "state of the art" in particular fields of research and to learn about the newest developments in emerging areas of science. Although fiscal constraints have made it impossible for DRG to approve all requested workshops, the Division nonetheless endorses the workshop concept, and feels that the exchange of information and ideas among experts is beneficial to study section members, invited participants from the scientific community, and the NIH staff. The DRG policy on study section workshops is outlined below.

Policy

1. Except in rare circumstances, study section workshops may occur only in conjunction with study section meetings, and preferably in the Washington area. Locations in other areas of the country are not encouraged but may also be considered for the reasons of importance of the site, and/or cost effectiveness.
2. A Referral and Review Branch (RRB) committee will evaluate each request on its scientific and fiscal merits. As described in the March 1987 edition of the Handbook for Executive Secretaries (pages 36-39, requests should include specific objectives, proposed location and dates, plans for publications, and budget estimate and breakdown (exclusive of study section meeting).
3. All requests for workshops should be addressed to the Deputy Chief, RRB and must be received two review rounds prior to the proposed workshop date.

| <u>Deadline</u> | <u>Workshop Date</u> |
|-----------------|--|
| January 2 | October/November of that year or later |
| May 1 | February/March of next year or later |
| October 1 | June of the next year or later |

FIGURE 21 (cont)

4. For each out-of-town workshop, the Executive Secretary should discuss the plans with appropriate NIH BIDs to determine if joint sponsorship and cost sharing are feasible. Another option to be considered is the alternative of an application for support via a Conference Grant (R13), with one of the members of the study section as nominal principal investigator. Using this latter option will involve the time table of the regular grant review cycle.

January 1985



Local Workshop Request

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date

From Executive Secretary
Study SectionSubject Budget estimate and breakdown for a proposed workshop in connection with
October Study Section meeting.To Dr. Irving Simos
Deputy Chief, RRB, DRG

has requested a workshop in connection with their October meeting. The meeting is to be held at the Holiday Inn Bethesda, Bethesda, MD. The additional cost for having a workshop breaks down in the following way:

Consultant fees-----seven speakers @ \$100-----\$700

Per diem-----seven speakers @ 75-----525

Travel

Stanford, CA-----r.t.-----\$925

Ithaca, NY-----r.t.-----254

New York, NY-----r.t.-----180

Boston, MA-----r.t.-----260

Toronto, CAN-----r.t.-----250

New Haven, CT-----r.t.-----164

Baltimore, MD-----r.t.-----20

\$2080-----2080

Total 3305

One, or possibly two speakers, will be attending the regular meeting.

One extra day for 16 study section members costs are:

Per diem-----16 @ 75-----1200 -----1200

3305
GRAND TOTAL 4505

PRE-WORKSHOP/CONFERENCE REPORT

Title : PLANT MOLECULAR BIOLOGY-GORDON CONFERENCE

Purpose : To serve as a medium for interaction between researchers focusing on basic and applied problems, and plant scientists using different techniques and working at various levels of the plant.

Meeting Dates : June 11-15, 1984

Location : Andover, New Hampshire

Chairperson : Dr. Robert B. Goldberg
Department of Biology
University of California
Los Angeles, California 90024

For Additional Information : Dr. Robert B. Goldberg

Sponsor(s) : National Institute of General Medical Sciences
Fogarty International Center

Staff Coordinator : Dr. Barbara Williams
Program Administrator
Genetics Program
National Institute of General Medical Sciences
Westwood Building, Room 918
Bethesda, Maryland 20205

Results to be Published : No

Chapter IV

PROCESSING OF APPLICATIONS BY THE REFERRAL SECTION

The Referral Section, DRG, is responsible for receiving and processing grant applications submitted to the Public Health Service (PHS), as well as for assigning such applications to an IRG for scientific merit review, and to an awarding unit for second level review and possible funding. This centralized organization ensures that the thousands of applications received each year are systematically logged in and routed to their appropriate destinations.

A. APPLICATION NUMBER

Essential to this process is the identification of each grant application by a five part number, which is supplied by the Referral Office to provide essential information about the application. An example of an identification number is: 1 R01 NS 12789-01A1. This number is made up of the following components:

| 1 | 2 | 3 | 4 | 5 | |
|-------------|----------|----------|--------|------------|-------|
| Application | Activity | Awarding | Serial | Suffixes | |
| Type | Code | Unit | Number | Grant Year | Other |
| 1 | R01 | NS | 12789 | 01 | A1 |

These components will be dealt with in sequence, highlighting those aspects that are most likely to be encountered by a Grants Assistant in DRG. A complete list of activities, review groups, awarding organizations and all their codes can be found in Activity Codes, Organizational Codes, and Definitions used in Extramural Programs (NIH Manual Issuance 4101), which is available from the Data Processing Section, Statistics and Analysis Branch, DRG, and is updated annually.

1. Application Types

Although not all types of applications undergo review, copies are sent to study section offices, and the Grants Assistant needs to be able to distinguish them. (See Types of Applications, Table 3.)

2. Activity Codes

The NIH has more than 100 grant-supported programs, all of which are given three digit activity codes. Those programs most often encountered by a Grants Assistant are described in Figure 24. Unless otherwise noted, Council review is required.

3. Awarding Unit

The awarding units can be identified from a two letter code in the application number (Table 4).

4. Serial Numbers

Serial numbers are assigned in sequence for each Institute.

5. Suffixes

- Grant Year - A two-digit number indicating the actual segment budget period of a project. The grant year number (01, 02, etc.) is preceded by a dash to separate it from the serial number, e.g., AM 12345-01, CA 00900-04. This series of years continues through succeeding renewals.
- Supplement - The letter "S" and related number identifying a particular supplemental award, e.g., S1, S2. Supplement designations follow the grant year but precede the amendment designation, e.g., AM 12345-01S1, CA 00900-04S1A1.
- Amendment - The letter "A" and related number identifying each amended application, e.g., A1, A2. Amendment designations follow the grant year or the supplement designation, e.g., DE 34567-02A1, DE 45678-01S1A1.

6. Application Contents

NIH application kits are available in the DRG Office of Grants Inquiries (Room 449, Westwood Bldg.) An application kit for each type of application should be kept in the study section office for reference (Table 5). The DRG Grants Inquiries Office responds to individual requests for application kits.

The contents of the most recently revised PHS 398 application folder include:

- o The instructions for completing form PHS 398;
- o Form PHS 398 and continuation pages; and
- o A mailing label addressed to the Division of Research Grants, NIH, Bethesda, Maryland 20892.

B. RECEIPT, PROCESSING, AND ASSIGNMENT OF GRANT APPLICATIONS*

Within the Referral Office, Project Control receives and processes applications, while the Referral Officers assign applications to IRGs, including DRG study sections, for scientific merit review and to awarding

* For contract proposals, see the Guide to the NIH Research Contracting Process HEW (NIH Publication No. 74-491). Contract proposals usually are processed and reviewed in the Institutes.

organizations for second level review and possible funding. Applications must be received by a specified receipt date to be eligible for review at any given study section meeting (Figure 25). Applications received after these dates must have an accompanying covering letter requesting a waiver of deadline and including the justification for such a request. The Referral Office will consider waivers of receipt dates for applications on an individual basis. No waiver will be granted prior to the receipt of an application, and no Executive Secretary has the authority to waive deadlines.

Upon receipt in the Referral Office, applications are processed as indicated in the chart entitled "Flow of a Competing Grant Application Through the DRG Referral Section" (Figure 26). The processing of individual research project grants (ROIs) is of most concern to DRG study sections, but nearly all other applications are processed in a similar fashion. Exceptions will be noted later.

1. Preliminary Processing of Type 1, 2, or 3 Applications (Prior to Receipt in Study Section)
 - a. Grant Application Receipt Unit (Mail Room). Application packets and any supplementary materials are received in the DRG Grant Application Receipt Room (Mail Room) where:
 - the application and other materials are date stamped; and
 - all documents are forwarded to the Receipt and Record Group of the Project Control Unit of the Referral Office.
 - b. Receipt and Record Subunit of the Project Control Unit. This unit reviews the non-scientific portions of the application for errors and consistency of available information; and also checks for special data, i.e., human subject certification, personal data form, and animal verification. A bar code is affixed on two application copies, one on the copy going to the Print Shop and one on the Project Control file copy. Staff then establish a record of receipt of the application by setting up a grant file with information consisting of type and activity code, principal investigator's name, grantee institution, title of the proposal, social security number, and Council date. The next step is to prepare application packages to be used by the Referral Officers. The IMPAC system of records is used to check the investigator's NIH record file for all pertinent information. Computer printouts of status records are inserted in the application folder. Quality control is maintained through the use of a special checksheet.

Letters or memoranda are often received before the application has been submitted. This material is labeled Awaiting Receipt of Application (ARA), is put in the ARA file, and is recorded on the computer. When the application is subsequently received, the Grants Clerk will be alerted and the material can then be inserted in the application package. ARA material is kept for 6 months; if the application is not received by that time, the material is discarded.

The application is checked for the correct number of copies, i.e., an original and six copies, for any extra material, and for the appropriate signatures. Then, the application and other materials are routed to the Assignment Section.

(1) Request for Applications (RFAs) These applications are also processed in the Assignment Unit, Referral Office. After assignment, they are entered into the IMPAC system in the Review and Control Sub-Unit. The same processing applies to RFAs as to applications going to DRG study sections.

(2) Renewal Operation, Receipt and Record Sub-Unit Funds must be requested annually, even though previously recommended. The face pages for all Type 5 (non-competing) applications are routinely mailed by the Renewal Operation Sub-unit, Project Control. They are mailed to the business office of the appropriate institution approximately 4 months before the beginning date of the next budget period and are to be returned directly to the appropriate awarding Institute within 2 months.

- c. Grant/Application Change Notice (901). An official change in an application, such as a change in study section or Institute assignment, a new Council date, withdrawal of the application, or a different application number, needs to be processed through a Grant/Application Change Notice (901). Study section or Institute staff complete a 901 notice, and then send it first to the Referral Office for approval, and then to the Project Control Unit for direct entry into the data system. All changes entered and recorded by the Project Control Unit will be announced to all affected organizations by means of a Resume of Transactions (ROT). These are generated daily by the Data Control Unit, Statistics and Analysis Branch.
- d. Assignment Unit. Assignment responsibilities are handled by Referral Officers, most of whom are Executive Secretaries of study sections. Each Referral Officer assigns applications to a specified group of study sections.

After determining that an application is relevant to the overall mission of the NIH, the Referral Officer examines the scientific content and assigns the application to an appropriate study section and Institute. These decisions are based upon written guidelines in the Handbook for Referral Officers and upon conflict-of-interest policy. Information received from Executive Secretaries and Institute staff as well as requests from applicants are given careful consideration. If the subject matter of an application is pertinent to the program responsibilities of two Institutes, a dual assignment may be made. One copy of the application (precopy) is then pulled out for the Executive Secretary of the assigned study section. The application folder and materials are returned to the Review and Control Group of the Project Control Unit for completion of processing.

- e. Review and Control Group of the Project Control Unit. Through a computerized logging system, this Group assigns serial and Institute numbers to all Type 1 and 9 applications. (Type 2, 3, 5 and 7 applications retain their existing numbers.) The Application Receipt Record is then updated by adding the study section and Institute assignment, the identification number, and the date of the Council to which the application is assigned.

Two copies (called work copies) submitted by the applicant are forwarded to the assigned study section, together with the computer printouts, correspondence, appendices, and any other material; these are enclosed in an application folder that can be used as a file. The Sub-unit records the final official assignment of applications by establishing a record in the IMPAC system for each competing grant application, and an assignment snap-out will be sent to the principal investigator and to the business office or grants contract office by the Statistics and Analysis Branch, DRG. At the same time, a copy of the application is forwarded to the Print Shop, where it is duplicated. The original is sent to the assigned Institute. The last copy of the application is retained in the Review and Control Sub-Unit Files.

The Review and Control Group is also responsible for sending a copy of the application to the Statistics and Analysis Branch, DRG, for data capture purposes and subsequently for incorporation into computerized documents used by the study sections and Institutes. This Sub-Unit is also responsible for ordering the appropriate number of printed application copies for the study sections and the Institutes.

- f. Print Shop. After the application has been printed, one copy of the requisition, and two printed copies of the application are sent to Project Control. Then the Print Shop distributes printed copies of the application to the study section and to the Institute(s) specified on the requisition.
- g. Data Control Unit (Statistics and Analysis Branch, DRG). Essential data are extracted from each application copy sent to this Unit for the computer printouts of worksheets, resumes, and summary statements that will be used later by the study sections and Institutes.

2. Processing of Other Types of Applications

- a. Type 7: Change of Grantee Institution. The processing is initiated by the awarding Institute. The investigator who is moving to another institution submits a new face page, budget pages, and facilities statement on form PHS 395, as well as form PHS 3734 (a statement from the original grantee relinquishing its interests and rights to the grant). The application is then assigned as a Type 7 and retains the same identification number. The awarding Institute sends the Type 7 directly to Data Control for processing. Such applications are not usually subject to study section review but are handled administratively by the Institute and presented to Council for confirmation.

- b. PL 480 Applications. PL 480 applications, which use U.S. owned excess currencies in a foreign country rather than funds in the NIH budget, are sent by the Fogarty International Center directly to the Referral Section where they are assigned to an appropriate study section for scientific merit review. (For additional information, see Chapter V.)

TABLE 3
TYPES OF APPLICATIONS

| Type | Description | IRG Review |
|------|--|-------------|
| 1 | New application | Yes |
| 2 | Competing continuation (renewal) application, i.e., a request for continued support after completion of the previously approved grant period | Yes |
| 3 | Supplement requesting additional funds during the current tenure of a research grant | Sometimes* |
| 4 | Noncompeting renewal of Research Career Awards (K06) | No |
| 5 | Annual request for continuation of previously approved support | No |
| 6 | Type 1 application for a training program transferred from one awarding unit to another | Yes |
| 7 | Application with committed support transferred from one grantee institution to another | Sometimes** |
| 8 | Type 5 application transferred from one awarding unit to another | No |
| 9 | Type 2 application transferred from one awarding unit to another | Sometimes |

* Many supplements are handled administratively by the awarding unit

** Type 7 applications are reviewed by an IRG only if the awarding unit requests it.

TABLE 4

AWARDING UNITS*

| Code | Awarding Organization |
|------|--|
| AA | National Institute of Alcohol and Alcoholism (NIAAA) |
| AD | National Institute of Alcohol, Drug Abuse, & Mental Health Administration (ADAMHA) |
| AG | National Institute on Aging (NIA) |
| AI | National Institute of Allergy and Infectious Diseases (NIAID) |
| AR | National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) |
| CA | National Cancer Institute (NCI) |
| DA | National Institute of Drug Abuse (NIDA) |
| DE | National Institute of Dental Research (NIDR) |
| DK | National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) |
| ES | National Institute of Environmental Health Sciences (NIEHS) |
| EY | National Eye Institute (NEI) |
| FD | Food and Drug Administration (FDA) |
| FP | Office of Family Planning (OASH) |
| GM | National Institute of General Medical Sciences (NIGMS) |
| HD | National Institute of Child Health and Human Development (NICHD) |
| HL | National Heart, Lung, and Blood Institute (NHLBI) |
| HS | National Center for Health Services Research (NCHSR) |
| LM | National Library of Medicine (NLM) |
| MH | National Institute of Mental Health (NIMH) |
| NS | National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) |
| NR | Center for Nursing Research |
| OH | National Institute of Occupational Safety and Health (NIOSH) |
| PG | Office of Adolescent Pregnancy Programs (OAPP) |
| RR | Division of Research Resources (DRR) |
| TW | Fogarty International Center (FIC) |

*Other PHS awarding units are listed in the Activity Codes booklet (Manual Issuance 4101).

TABLE 5

GRANT APPLICATION KITS

| Major Types of Applications | Kits |
|--|--|
| Individual Fellowships (F32 & F33) (National Research Service Award-NRSA) | PHS 416-1 |
| Institutional Fellowship (T32) (National Research Service Award-NRSA) | PHS 6025 |
| Program Project (P series) | PHS 398 |
| Regular Research Grant (R01) | PHS 398 |
| Research Career Development Award (K04, K07, K08) | PHS 398 & Supplemental Instruction Booklet PHS 2557-1) |
| Small Business Innovation Research (SBIR) Program (R43 & R44) | PHS 6246-1 |
| Academic Research Enhancement Award (AREA) | PHS 398 |

FIGURE 24

ACTIVITY CODES

- F05 International fellowships provide training in the U.S. for non - U.S. citizens from overseas who hold a doctoral degree or its equivalent in a health science field. The initial review is by a DRG fellowship study section, which is followed by a Fogarty International Center staff review.
- F06 Senior international fellowships provide opportunities to outstanding mid-career faculty members from U.S. schools of medicine, osteopathy, dentistry, and public health with demonstrated productive scholarship and recognized stature in their profession to go abroad to study and share their expertise. The initial review is by a DRG fellowship study section, which is followed by Fogarty International Center staff review.
- F32 The National Research Service Award postdoctoral fellowship is presented to an individual who is sponsored by an established investigator for a period of up to 3 years. It provides newly graduated scientists and physicians with additional research training to broaden their scientific skills and research potential in specific health-related areas. These fellowship applications are reviewed by DRG fellowship study sections but are not reviewed by council; the second level-review is conducted by an Institute staff committee.
- F33 The National Research Service Award for senior fellows provides opportunities for experienced scientists to make major changes in the direction of their research careers, to broaden their scientific background, to acquire new research capabilities, to enlarge their command of an allied research field, or to take time from regular professional responsibilities to increase their capabilities for engaging in health-related research. Normally such awards are made for a period of 12 months; the period of award may not exceed 24 months. These applications are reviewed by DRG fellowship study sections and then by an Institute staff committee.
- K04 The Research Career Development Award (RCDA) is intended to foster the development of scientists who have demonstrated outstanding research potential for independent research careers in the health-related sciences. The RCDA supplies a candidate's salary for 5 years, during which time the candidate is expected to continue his or her scientific development as an independent investigator. RCDA applications are first reviewed by DRG study sections.
- P01 The program project grant is a broadly based multidisciplinary research effort with a well-defined central research focus or objective. This type of grant consists of a number of inter-related projects that contribute to the program objective. The responsibility for leadership of the program resides with the principal investigator or program director who must possess

FIGURE 24 (cont)

demonstrated scientific and administrative competence. Applications usually are first reviewed by Institute IRGs.

- R01 The individual research project grant application is the type of research application most often reviewed in DRG study sections. This program is designed to support the research efforts of individual scientists on discrete, circumscribed projects of their choosing. Awards are made for periods of up to 5 years.
- R03 The Small Grants Program, a one year, non-renewable grant, provides support for pilot projects, testing of new techniques, or feasibility studies of innovative and high-risk research. At the present time, only the National Institute of Aging, the National Institute of Dental Research, the National Eye Institute, and the Division of Research Resources award such grants within the NIH. The National Institute of Mental Health in the Alcohol, Drug Abuse, and Mental Health Administration also has such a program.
- R13 The Conference Grant supports national or international meetings, conferences and workshops. DRG study sections or Institute IRGs review these applications.
- R15 Academic Research Enhancement Award (AREA) is designed to develop research in educational institutions in the United States which provide the baccalaureate training for a significant number of our research scientists, but which historically have not been major participants in NIH programs. These grant awards are for the support of new or expanded health-related research projects conducted by faculty in institutions that are presently not research intensive. The AREA will enable qualified individual scientists to receive support for feasibility studies and other small scale research projects.
- R29 The First Independent Research Support and Transition Award (FIRST) is to provide a sufficient initial period of research support for newly independent biomedical investigators to develop their research capabilities and demonstrate the merit of their research ideas. These grants are intended to underwrite the first independent investigative efforts of an individual; to provide a reasonable opportunity for him/her to demonstrate creativity, productivity, and further promise; and to help effect a transition toward the traditional types of NIH research project grants. FIRST awards generally will provide funds for five years during which time the newly independent investigator with a promising, meritorious proposal can provide evidence of significant and innovative contributions to laboratory or clinical science disciplines in biomedical research.
- R43 The purpose of the Small Business Innovative Research Program (SBIR) is to stimulate technological innovation, use small businesses to meet Federal R&D needs, increase private sector

FIGURE 24 (cont)

commercialization of innovations derived from Federal R&D funds, and encourage participation by minority and disadvantaged persons in this area. The SBIR Program consists of three phases. Phase I (R43) establishes the technical merit and feasibility of ideas that may ultimately lead to commercial products or services. Awards are for approximately \$35,000 in direct costs for a period normally not to exceed 6 months. Phase II (R44) is an indepth development of ideas proposed in Phase I and likely to result in commercial products or services. Special consideration is given to projects demonstrating prospective private capital commitments for commercial applications. Only Phase I awardees are eligible to apply for Phase II funding. Phase II awards normally may not exceed \$500,000 including both direct and indirect costs for a period normally not to exceed 2 years. For Phase III, applications are to include the involvement of private capital for commercializing the results of R&D funded by a Federal agency, or the involvement of non-SBIR funded contracts with a Federal agency for products or processes intended for use by the U.S. government. SBIR applications are initially reviewed by DRG study sections.

- R44 Small Business Innovation Research (SBIR) Award--Phase II supports continuing research initiated with Phase I support. Only Phase I awardees are eligible to apply for Phase II support.
- S10 Shared Instrumentation grants enable applicants to acquire new, or update existing, research instruments that cannot be justified fully for use on a single project but can serve projects on a shared basis. At present, only the Division of Research Resources (S10) and the National Institute of General Medical Sciences (P41) award these grants. The initial review is a DRG special study section.
- T35 Short-term National Research Service Awards are first reviewed by DRG special study sections. These awards are made to institutions in order to support research training for students in professional schools for discrete periods of up to 3 months. The program is designed to ameliorate the future shortage of clinical investigators by attracting highly qualified professional students into biomedical and behavioral research careers.

Of the many other activities supported by the NIH, the following are of particular interest even though they may not be assigned to DRG study sections.

- Animal resource (P40) and biotechnology resource (P41) grants provide resource support to qualified investigators regardless of their scientific discipline or the disease orientation of their research programs. Another resource related program, the R24, is designed to improve the capability of resources to serve biomedical research.

FIGURE 24 (cont)

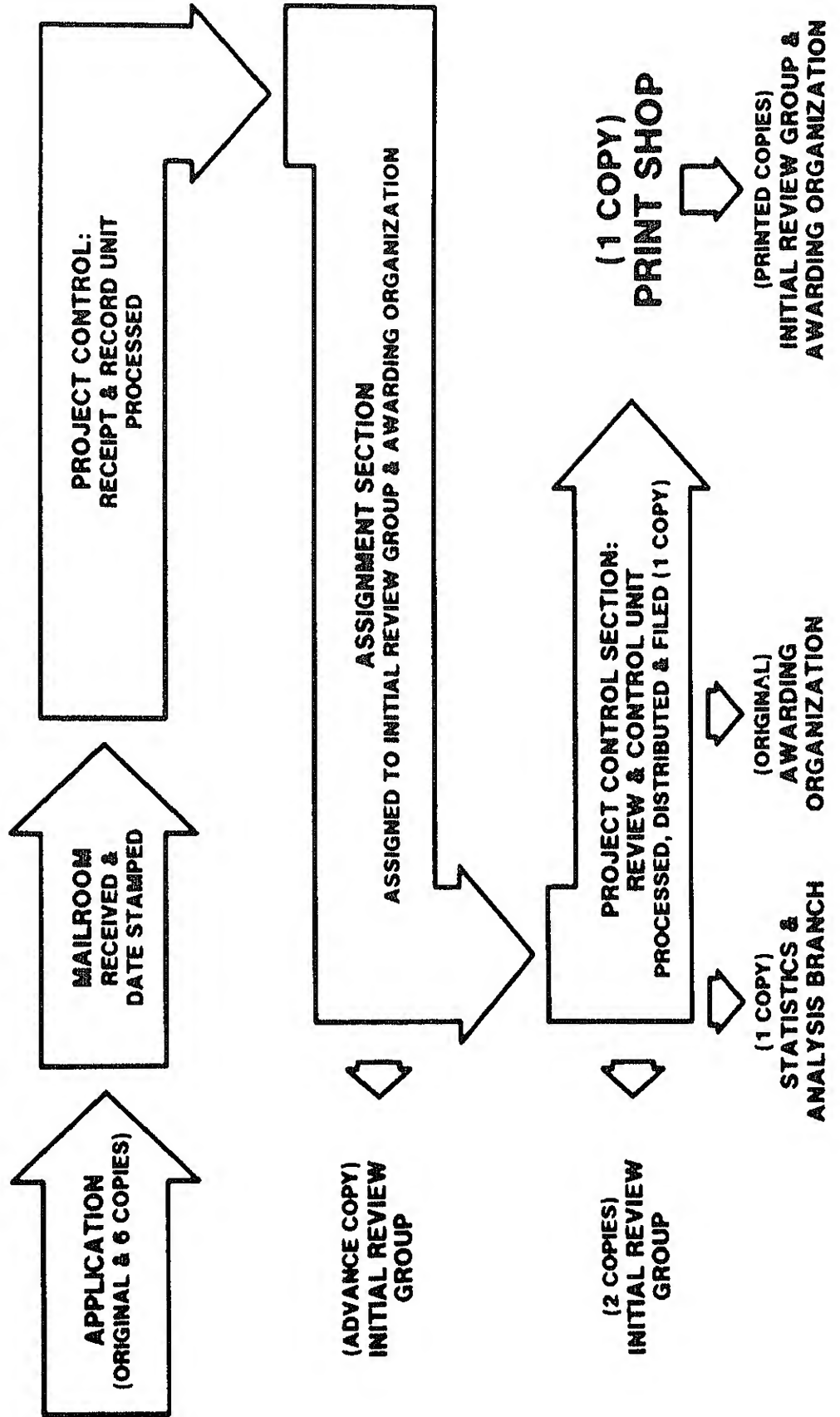
- Research demonstration and dissemination projects (R18s) support health service activities and foster the spread of existing knowledge to control specific diseases. R21s are limited programs to encourage development of new research activities in specific program areas. R25s are education projects to support educational, informational, or training aspects of a program in a given research or clinical area. While the general goals of these three programs are similar throughout the NIH, it is advisable to read the specific program announcements in the NIH Guide for Grants and Contracts, because variations in program goals may exist among the Institutes.
- A specialized center (P50) is generally developed in response to an announced need by an Institute and is directed to research on a specific disease entity or biomedical problem. A comprehensive center (P60) is designed to bring together community resources, such as hospitals, primate colonies, or regional centers, in order to foster biomedical research and community education concerning a given disease. Projects from P01, P50 and P60 applications are often submitted also as regular research grants.
- The Institutional National Research Service Award (T32), or institutional fellowship, has similar objectives as the F32, but is made to an institution, which then selects the individuals to be trained under the program.
- The Academic Award (K07) is designed to create and encourage a stimulating approach to disease curricula that will attract high quality students, foster academic career development of promising young teacher-investigators, develop and implement excellent multidisciplinary curricula through interchange of ideas and enable the grantee institution to strengthen its existing teaching program.
- The Clinical Investigator Award (K08) is for promising medical scientists, who have demonstrated their potential for developing into independent investigators, or faculty members, and who will pursue research aspects of categorical areas applicable to the awarding unit and aid in filling faculty gaps in these shortage areas within health professional institutions.
- The Physician Scientist Award supports either newly trained clinicians nominated by an institution for development of independent research skills and experience in a fundamental science (K11), or these individuals appointed by an institution to work within the framework of an interdisciplinary research and development program (K12).

APPLICATION RECEIPT DATES, REVIEW AND AWARD SCHEDULE

| Application Receipt Dates | | | Initial Review Group Dates | National Advisory Council/ Board Dates | Earliest Possible Beginning Dates |
|---|--|---|--|--|-----------------------------------|
| Jan. 10 May 10 Sept. 10 for All individual MRSA applications. All new and competing continuation Institutional MRSA Training grant applications. (Individual MRSA applications are not reviewed by Council. Their start dates are therefore approximately 4 months earlier than indicated.) | Feb. 1 June 1 Oct. 1 for All new research grant applications, unless specified differently in a Program Announcement or Request for Applications. Career Development awards and Conference grant applications. New and competing continuation Project and Center applications. | Mar. 1 July 1 Nov. 1 for Competing continuation & supplemental research grant applications. | Apr. 15 Aug. 15 Dec. 15 for Small Business Innovation (SBIR) Program, both Phases. (Phase II applicants must have completed a federally-funded Phase I project.) | May/June Oct./Nov. Feb./Mar. | Dec. 1 Apr. 1 July 1 |

All applications must be received by the above dates. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following workday. The receipt date will be waived only in extenuating circumstances. To request such a waiver, include an explanatory letter with the signed completed application. No waiver will be granted prior to receipt of the application. It is in an applicant's best interest to submit early and avoid the otherwise unavoidable rush associated with announced receipt dates.

FLOW OF A COMPETING GRANT APPLICATION THROUGH THE DRG REFERRAL SECTION



STUDY SECTION OFFICE: PROCESSING OF APPLICATIONS

A. INITIAL PROCESSING BY THE GRANTS ASSISTANT

Since many of the procedures described in this section of the Handbook vary among study sections, the following instructions are meant to serve only as guidelines. The practices already in existence in a study section may, of course, be continued. Because a new Grants Assistant may not fully understand the basic principles of research grant review until after having worked a full three rounds, that person should not be too quick to change existing procedures.

1. Study Section Log and Application Receipt Record

Upon receiving an application from Project Control, the Grants Assistant should maintain a study section log to record information on all applications to be reviewed at a given meeting. The log should include the following items:

- Application number;
- Name of principal investigator or candidate;
- Due date of the printed copies from the Print Shop (if the printed copies have not been received within 5 working days of the due date printed on the label at the top of the yellow copy of the Project Control Checksheet (Figure 27), the Grants Assistant should notify Project Control who will, in turn, contact the Print Shop); and
- Other notations, such as transfers or withdrawals.

A suggested study section log format (Figure 28) consists of a series of pages with a separate page for each Institute, and is usually prepared when the work copies of the applications are received. Deferred applications should be included in the log.

The Project Control Unit notifies the applicant's institution of the application number and the assigned study section, Executive Secretary, study section address, and phone number. When there is a transfer of assignment and a 901 is issued, a computer-generated letter is sent to the principal investigator informing him of the change.

2. Advance and Work Copies of Applications

The Grants Assistant or the Executive Secretary should check the preliminary assignment box in the Referral Office as soon as possible after the receipt date for applications to see if there are any advance copies assigned to the study section. (In some instances the assignment officer will deliver advance copies.) It is important for the Executive Secretary to examine these applications to check for appropriateness of assignment before the Grants Assistant processes the applications.

Work copies of each application are received before duplicated copies arrive from the Print Shop. A folder containing the yellow copy of the Project Control Checksheet (Figure 27), correspondence, and other supportive materials will also be sent at that time. Special items on the folder cover should be brought to the attention of the Executive Secretary. The due date for printed applications will be noted on the folder cover.

Two work copies of each application are normally included in the package; these work copies may be used for early mailings to study section reviewers assigned to the application.

If there is any correspondence or appendix material with the work copies, the original is forwarded to the primary Institute, with copies placed in the study section file and in the Executive Secretary's workbook.

3. Study Section Work Record

Most study sections use some type of work record or checklist for individual applications (Figure 29). It is recommended that these work records or checklists not be kept in the file. The following information is normally included:

- Study section name and date of meeting;
- Identifying information, such as the application number, name of principal investigator, institution, and location;
- Any information omitted from the application or special problems;
- Assignees;
- Executive Secretary's indication of any additional information to be obtained from the applicant, any outside opinions to be obtained, and the due dates for additional information to be received or other action taken; and
- Notes about the distribution of the various materials.

4. Executive Secretary's Workbook

An Executive Secretary may require a complete set of applications and supplemental materials for every meeting. Depending on the Executive Secretary, applications are inserted in looseleaf binders, in folders, or in accordion files. The Grants Assistant is responsible for preparing this workbook and keeping it current.

5. Study Section Records

If the study section maintains a Roladex or Index card file on all applications, the Grants Assistant should prepare these records when applications are received and processed. A useful technique is to

stick computer labels, which contain complete, up-to date information, on those cards. The Grants Assistant can automatically retrieve printed labels by accessing TSO. (Instructions are available in the User Resource Office.) Additional information about the records and files needed by each study section is contained in Chapter XVI.

6. Meeting Files

Applications for a current meeting should always be kept together and separate from other files. While the entire file can be taken to a local meeting, this is not desirable, and should be discussed with the Executive Secretary.

EXAMINATION OF APPLICATIONS BY THE GRANTS ASSISTANT

Prior to the Executive Secretary's review, the Grants Assistant screens each application for possible administrative problems. In general, check the application for completeness. The questions below cover the areas the Executive Secretary may need to know about for possible follow-up.

- Is Section 4 on page 1 completed? Are human subjects checked yes on page 1? Is an Exemption claimed? If needed, are the human subjects 6 points present (Figure 30)? Does the institution have an Assurance of Compliance number (Figure 31)?

If the IRB approval date is marked pending on page 1, a proper certification must be received prior to the study section meeting, but not more than 60 days after the receipt date; otherwise, the application is administratively deferred. For further information, see Item 4 of the instructions for PHS Form 398 (revised 9/86). Note: If an exemption is claimed, the applicant needs to justify the exemption in the application. (For more detailed information on the protection of human subjects, see Chapter XV.)

- Is Section 5 on page 1 completed? Does the proposed research involve vertebrate animals? If so, are the five points addressing animal care and use included at the end of the Methods Section in Section F of the application (Figure 32)? If needed information is not provided in the application, it should be requested and obtained from the applicant immediately. If the IACUC approval date on page 1 is marked pending, the verification must be renewed prior to the study section meeting, but not more than 60 days after the receipt date; otherwise, the application is administratively deferred. A sample form requesting animal subject information is included in Figure 33. For further information, see Item 5 in the instructions for PHS Form 398 (revised 9/86). (For more detailed information, see Chapter XV.)
- Are the personnel listed on page 2 of the application and on the detailed budget page(s) free of any conflict of interest with study section members and special reviewers? On a fellowship (F32) application, check for conflict of interest involving the sponsor of

the application. (For a more detailed explanation of conflict of interest, see Chapter XV.)

- Have the checklists, appendices, and supplemental materials referred to been received?
- Are the budget pages complete?
- Are there confidential budget pages? These are for NIH use only. Under no circumstances should confidential budgets be sent to study section members. Project Control sends a copy of the confidential budget to the appropriate Institute(s) at the same time the application is sent to them.
- Is the biographical information included for all key personnel?

A sample letter requesting additional information from the applicant is shown in Figure 34.

C. PROCESSING OF NEW RESEARCH PROJECT GRANT (1 R01) APPLICATIONS

To process new research project grant applications, the Grants Assistant should perform the following five procedures:

- (1) Upon receipt, enter each application in the study section log;
- (2) When the duplicated applications have been received, be sure they have been delivered to the proper study section; if not, see that the appropriate study section receives them;
- (3) Prepare a study section work record or checklist;
- (4) Type or attach a label to the index or roladex card if the study section maintains these records; and
- (5) Prepare a file folder. The folder should be marked with the basic application number and the principal investigator's last name (first initial optional), for example, AM 12345 KOLODNY, V. (File labels can be obtained through computer program SSR.)

The most common procedure is to file the contents (application, summary statement, correspondence and notice of grant award) chronologically. Some study sections find it useful to use backers; others organize files without backers.

Extra copies of the application and an adequate supply of summary statements for future use should also be kept in this folder. In order to conserve space, it is suggested that no more than three extra copies of the current application and an adequate supply of summary statements be kept in this folder.

D. PROCESSING OF COMPETING CONTINUATION (2 R01) OR SUPPLEMENTAL (3 R01) RESEARCH PROJECT GRANT APPLICATIONS

Competing continuation (Type 2) and supplemental (Type 3) applications are processed in the same manner as new applications, except that the file already exists. Previous summary statements and other background information on these applications may be sent to study section assignees or members prior to the study section meeting and should be recorded on the study section work record.

Progress Reports

Progress reports are an integral part of all competing continuation and supplemental applications. If a progress report is requested from an applicant, the investigator sends the required number of copies directly to the study section. The Grants Assistant sends the original to the Institute.

E. PROCESSING OF OTHER TYPES OF APPLICATIONS (Guidelines see Chapter VI)

1. Small Business Innovative Research (SBIR-R43 & R44) Applications

SBIR applications are processed in the same manner as research project grant applications. Few of these institutions will have a general assurance filed with the NIH in regard to human subject review committees. If the application indicates human subjects are involved and no exemption is claimed, a completed HHS-596 (Figure 35) and the 6 points are required before the application may be reviewed.

2. Research Career Development Award (RCDA K04) and FIRST Independent Research Support and Transition (FIRST-R29) Applications

RCDA and FIRST applications are processed in the same way as research project grant applications except that reference letters are required. The table of contents gives the page number on which a list of references can be found. At least two of these letters must be received prior to the meeting for the review to be completed.

The Grants Assistant should keep a record of the references received for the applicant. Sufficient copies should be duplicated for the application's assignees and for other members of the study section if the Executive Secretary so desires. Copies of these letters are not to be retained in the files after the study section meeting. The original reference letters should be forwarded to the appropriate Institute(s) to which the application is assigned.

3. Academic Research Enhancement Award (AREA-R15) Applications

AREA applications are processed in the same manner as research grant applications.

4. Postdoctoral Fellowship (F32) Applications

Postdoctoral fellowship applications are processed in the same manner as RCDA applications. At least two reference letters must be received prior to the meeting for the review to be completed. The original letters are sent to the appropriate Institute(s) and the copies are destroyed after the study section meeting.

5. Deferred Applications

All applications deferred at a previous study section meeting should be put with materials for the current meeting. Additional printed copies of the application must be ordered by the Grants Assistant for the study section and the appropriate Institute. (See the Distribution Guide, Figure 36.) Copies of revised budgets and pertinent additional information may also need to be duplicated.

A Council may defer an application that was not originally deferred by the study section. If the application is returned to the same study section for re-review, the Grants Assistant should have copies of the application and other materials duplicated again.

Councils will sometimes defer an application but suggest review by a different study section. In this case, the Referral Office acts on the matter and takes care of any transfers. The new study section has the responsibility for duplicating the application and other materials.

6. Change of Study Section

When an application is transferred from one study section to another, copies of the application and the file must also be transferred. A record of the transaction should be entered in the study section reference files (i.e., summary statement books, office cards, roladex). The new study section is responsible for informing the principal investigator about the transfer.

A transfer is not official until the new study section has received the computerized Application/Grant Change Authorization Notice (Figure 37) and Daily Transaction List (Figure 38) (See also Section L below.)

7. Change of Institution

- a. Well Before Study Section Meeting. When applicants move to another Institution, they usually also transfer their research projects. The applicant sends the study section revised pages signed by an official at the new institution and a releasing statement from the old institution, also signed by an official. If the revised pages arrive well before the review, the Grants Assistant makes copies for the Executive Secretary and reviewers. If the application is Type 1 (never awarded), then the original and four copies should be forwarded to Project Control where a new number is assigned. If the application is a Type 2 (has been awarded previously), one copy is sent to Data Control, Westwood Building, Room 103, where the IMPAC

system will be updated. The application number will stay the same. The Grants Assistant must also update the study section workfile before releasing information to IMPAC.

- b. Before the Study Section Review but Close to the Study Section Meeting. If the revised pages for the change of institution arrive close to the meeting, the study section reviews it under the present number. The Grants Assistant notifies Data Control and corrects the study section workfile before releasing the information to IMPAC. If the application was a Type 1 (never awarded), then Project Control needs to give the application a new number.
- c. After Study Section and Council Review. If the institution change is made on a Type 1 (never awarded) application after the complete review cycle, Project Control assigns a new number and sends a set of the revised pages to the study section and the appropriate Institute. These applications are not re-reviewed. If the institution change is made on a Type 2 application, the appropriate Institute is responsible for any changes to be made.

Note: Any time an application number changes:

The new number should be added to the top of the extra applications and summary statements; and

All study section records should be changed. A cross-reference is suggested in the summary statement books, and a new rolodex or index card should be typed indicating the new and former numbers.

8. PL-480 Applications

In the rare instances when these applications are reviewed by DRG study sections, a covering memorandum from the Referral Office is attached to the application explaining the administrative procedures involved, including the duplication of applications. The review of these applications is to be noted in the study section minutes, even though the applications are not listed on the resume of initial review group recommendations. Study section recommendations are forwarded, in memorandum form, through the Deputy Chief for Referral, RRB, to the Fogarty International Center. DHHS policies concerning assurances of protection of human subjects involved in research also apply to PL-480's. Pertinent background information may be obtained through the Fogarty International Center. PL 480 applications should be manually added to all study section listings.

9. REPRINTS AND APPENDICES

Reprints, progress reports, and appendices, which may be submitted with any type of application, are usually received in limited numbers. The Grants Assistant sends one copy to each assignee, and one copy to the appropriate Institute(s), and files one copy. To conserve space, reprints and appendices are not to be retained in study section files after the study section meeting. Reprints are not to be xeroxed.

G. DUAL ASSIGNMENTS

If a dual assignment is made after the application has been printed and distributed, the Grants Assistant must order copies for the second Institute. Information concerning this change of assignment will appear on the Daily Transaction List. (See Section L below.)

H. DISTRIBUTION OF APPLICATIONS WITHIN THE OFFICE

After the applications have been processed in the study section office, the Grants Assistant distributes them as follows:

- Copies for the official study section file;
- One copy for each study section assignee;
- Copies for the necessary workbooks (study section members, two observers, the Executive Secretary, and the Grants Assistant);
- Miscellaneous copies. (See the Distribution Guide, Figure 36, for instructions that may apply to certain applications.)

Most study sections have sectioned wood or metal shelves (collators), which can be labeled with names and application numbers. Material intended for assignees can thus be assembled in a special area of the collator for preliminary mailings. Material should be placed on the shelves first alphabetically by Institutes and then numerically within each Institute.

The files and shelves must be labeled clearly so that anyone needing copies of applications can find them quickly in the absence of the Grants Assistant.

I. REVISED OR ADDITIONAL APPLICATION PAGES

If a principal investigator submits revised or additional application pages, the complete application number and the word "REVISED" should appear at the top of the first page. Duplicated copies should be sent to the study section members and attached to all study section file copies, and the original should be sent to the Institute.

J. REVISED BUDGETS

If a principal investigator submits a revised budget before the study section meeting, the Grants Assistant distributes the revised budget pages (Section I above) and does an Official Change of Data procedure on the Interface System. If a revised budget is submitted after the study section meeting, the Grants Assistant notes on the first page that it was received after the study section meeting and forwards it to the Institute. In this instance, an Official Change of Data procedure is not made. In either case a signed face page of the application or a letter signed by the appropriate institutional official should be received with the revised budget. Otherwise, the principal investigator is notified.

K. WITHDRAWALS

A withdrawal letter from a principal investigator should be cosigned by the appropriate institutional official. However, a withdrawal letter from an institutional official need not be signed by the principal investigator, but the principal investigator should be notified of the letter. Otherwise the Grants Assistant sends a letter to the principal investigator, with a copy to the appropriate institutional official, acknowledging receipt of the withdrawal letter and requesting the official's co-signature. After the official withdrawal letter has been received, the Grants Assistant sends the original to the Institute and forwards a copy to the Referral Section attached to a completed Request for Assignment Change(s) form (Figure 37) for processing.

If the letter comes in before the study section meeting, the Executive Secretary must notify the particular assignees that the application need not be reviewed. If the withdrawal letter arrives after the meeting, the Executive Secretary does not need to prepare a summary statement, and the Institute is responsible for sending acknowledgment of the withdrawal. However, if the summary statement has already been completed, it should be sent to the Institute.

L. PROCEDURE FOR MAKING CHANGES IN APPLICATIONS

1. Daily Transaction List

The Daily Transaction List (Figure 38), prepared by the Systems and Data Management Section, Statistics and Analysis Branch, DRG, is a continuing list of administrative changes on grants, pending applications, extramural meetings, and certain other items of administrative interest. Whenever the Grants Assistants receive such a list and an Application/Grant Change Authorization Notice (Figure 39), they will know the change is official and should make the appropriate changes in the study section records.

a. Included in Daily Transaction List

- Official changes in budget, principal investigator, sponsor of a fellowship, number of years requested, etc.
- Official changes of study section action on resumes, summary statements, etc.

b. Not Included

- Changes of dates on new applications
- Changes in the scientific component of the application
- Misspellings or shortened project titles
- Changes involving Recombinant DNA Code, human subjects, etc.

2. Submission of Changes

At various times during the review process, the Grants Assistant will need to send information on changes to the Data Processing Section. Some of these changes are processed through the Referral Section using the Request for Assignment Change(s) form (Figure 37), including changes in study section, Council date, administrative deferrals, application number, secondary Institute assignments, and withdrawals. Other changes are entered directly into the computer; among these are changes in human subject and animal codings, the applicant's name, the address of applicant, the start date, the budget, and, for fellowships, the years/months requested. Many of these changes will be initiated in the study section, but Institute and Referral staff can also initiate such changes. In order to keep everyone informed of changes, a resume of transactions (ROT) is sent periodically to the office. If the changes are submitted prior to the study section meeting, the changes will be entered into the computer system and will be automatically reflected on the resumes and summary statement tops. Otherwise, the Grants Assistant may have to enter the changes in the computer after the study section meeting, before releasing post-meeting information to the IMPAC system.

M. HISTORY FILES

The Referral Section (Room 248) has computer printouts of all competing applications. These printouts are divided into Council date groupings and are listed alphabetically by principal investigator. When in doubt about the receipt of an application, the Grants Assistant should check the printouts.

FIGURE 27

PROJECT CONTROL CHECKSHEET

| TYPE | PROGRAM | INSTITUTE | SERIAL NUMBER | YEAR | SUPPL | AMENC |
|---|------------------------------------|--------------------------|--|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Title of proposal | | | STUDY SECTION | | FORMERLY | |
| Investigator's name, etc | | | | | | |
| Social Security Number | | | Council date | | | |
| YES NO | Change of applicant organization | | Title review & assignment by | | | |
| YES NO | Relinquishment statement | | | | | |
| Type of organization | | | INSTRUCTIONS FOR PROCESSING: TITLE 1. CHANGE TO _____ _____ 2. DELETE FROM _____ _____ 3. ADMINISTRATIVE COPIES ONLY _____ | | | |
| Name/title, authorized official | | | | | | |
| Name/title/address - financial officer | | | | | | |
| Personal signatures | | | | | | |
| Facilities and commitment statement | | | | | | |
| Notarization Form 151 | | | | | | |
| Number references | | | | | | |
| Original plus _____ copies | | | | | | |
| Accompanying correspondence | | | | | | |
| ARA | | | | | | |
| Number of pages | | | | | | |
| YES NO | Checklist | | | | | |
| Investigator cards | | | | | | |
| YES NO | Human Subjects Statement (HHS 596) | | | | | |
| YES NO | Appendix | | | | | |
| YES NO | Extra material Room 240 | | | | | |
| Comments by Project Control: | | | SPECIAL DISTRIBUTION _____ V A _____ MEETINGS _____ DUAL _____ OTHER (Specify) | | | |
| Checked by | | | | | | |
| Note to Executive Secretary. | | | | | | |
| IRG Member <input type="checkbox"/> YES <input type="checkbox"/> NO | | | | | | |

CHECKSHEET - PROJECT CONTROL

Suggested Study Section Log Format

| Appl. No. | Investigator | Work Copies | Printed Copies | Other |
|--------------|-----------------|----------------|-------------------|-------|
| 60639-01 | Smith, John B. | | | |
| 60955-01 | Doe, Jane S. | | | |
| 70366-02 | Bender, Tim O. | | | |
| 80277-02 | Gleem, Susan K. | | | |

FIGURE 29
STUDY SECTION CHECKSHEET

DATE OF MEETING _____ APPLICATION NO. _____

APPLICANT _____ FOREIGN _____

INSTITUTION _____

TITLE _____

HUMAN SUBJECTS _____ EXEMP. NO. _____ CERTIF. HHS 596 _____ 6 POINTS _____

OTHER GRANTS: ACTIVE _____ PENDING _____ ASSIGNEES _____

CONFLICT OF INTEREST _____

VERTEBRATE ANIMALS _____

ANIMAL STATEMENT (pg. #) _____

RECOMBINANT DNA _____

POTENTIAL BIOHAZARDS _____

DISTRIBUTION

| | ASSIGNEES | SS | CHM | FILE | INST | WKBK |
|---------------------|-----------|----|-----|------|------|------|
| Pending Appln. | | | | | | |
| Background Appln. | | | | | | |
| Summary Sheet | | | | | | |
| Reprints | | | | | | |
| Manuscripts | | | | | | |
| Progress Report | | | | | | |
| Current Budget | | | | | | |
| Confidential Budget | | | | | | |
| Appendix | | | | | | |
| Other | | | | | | |
| | | | | | | |

| ADDITIONAL INFORMATION | REQ | RECD | ASSIGNEES | SS | CHM | FILE | INST | WKBK |
|------------------------|-----|------|-----------|----|-----|------|------|------|
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| OUTSIDE OPINION | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

NOTES: _____

E. Human Subjects. If you have marked Item 4a on the Face Page of the application "YES," and designated no exemptions from the regulations, address the following six points.

1. Provide a detailed description of the proposed involvement of human subjects in the work previously outlined in the experimental design and methods section. Describe the characteristics of the subject population, including their anticipated number, age, ranges, sex, ethnic background, and health status. Identify the criteria for inclusion or exclusion. Explain the rationale for the involvement of special classes of subjects, if any, such as fetuses, pregnant women, children, human *in vitro* fertilization, prisoners or other institutionalized individuals, or others who are likely to be vulnerable.
2. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.
3. Describe plans for the recruitment of subjects and the consent procedures to be followed, including the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the institutional review board (IRB) has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent. The consent form, which must have IRB approval, should be submitted to the PHS only on request.
4. Describe any potential risks—physical, psychological, social, legal, or other—and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.
5. Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects.
6. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

If you have marked Item 4a on the Face Page of the application "YES" and designated exemptions from the human subjects regulations, provide sufficient information to allow a determination that the designated exemptions are appropriate.

If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration.

Although no specific page limitation applies to this section of the application, be succinct.

FIGURE 31
GUIDELINES FOR CHECKING HUMAN SUBJECTS CERTIFICATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20205

MARCH 1985

LIST OF INSTITUTIONS WHICH HAVE ESTABLISHED A
MULTIPLE PROJECT ASSURANCE OF COMPLIANCE
WITH HHS REGULATIONS (FORMERLY A GENERAL ASSURANCE)
FOR THE PROTECTION OF HUMAN SUBJECTS
(45 CFR 46, AS AMENDED MARCH 8, 1983)

1. INCOMING PROPOSALS - GRANTS OR CONTRACTS

a. If the professional review of a proposal indicates that the project does not involve human subjects (as indicated on No box on face/signature page of application), as defined in 45 CFR 46, the application can be processed without further regard to the question of institutional assurances.

b. If the professional review of a proposal indicates that the project does involve human subjects (as indicated on Yes box on face/signature page of application), the next step is to determine whether the institution has indicated in item 4 that the research is exempt as defined in 45 CFR 46.101(b) or has indicated that the Form HHS 596 is enclosed with the application.

-If the institution has indicated that the proposed research is exempt from 45 CFR 46, and professional review of the proposed research is in agreement with the institutional designation of exemption, the application can be processed without further regard to the question of institutional assurances.

-If human subjects are involved, the Form HHS 596 must be reviewed to determine the status of or need for an assurance.

c. Draft requests for proposals (RFPs or RFAs) should be reviewed to determine whether the proposed research will involve human subjects. If human subjects will be involved and the research is not exempt from 45 CFR 46 as defined at 46.101(b), the RFP should include the "Notice to Offerors" required by 41 CFR 3-4.5504(a). Offerings and proposals submitted in response to the RFP should be handled as in 1.b. above.

d. Operating agencies may define "submission date" to fit administrative requirements. It is suggested that solo source responses to RFPs should be considered to be submitted as of the closing date of the RFP and should then be handled as in 1.b. above.

e. Competitive responses to RFPs should be considered to be submitted as of the date of submission of the best and final offer, after establishing the zone of consideration or source selection, and should then proceed as in 1.b. above.

2. ASSURANCE STATUS AND SUBMISSION OF CERTIFICATIONS - Whenever possible, the review and approval by Institutional Review Boards (IRBs) should occur prior to submission of the application or proposal and a certification to that effect should be included in or with the application or proposal itself, on Form HHS 596 (Rev. 1/82). Under no circumstances will the review of an application by the Department of Health and Human Services be completed until certification is received.

Institutions with an approved Multiple Project Assurance (formerly a General Assurance) must submit certification within 60 days after the deadline or submission date for which the application or proposal was submitted. Item 4 of the Form HHS 596 must indicate that the institution has an approved assurance of compliance on file, giving the identification number of the assurance under which the application or proposal was reviewed and approved and the identification number of the IRB which approved the application or proposal.

Institutions without an approved Multiple Project Assurance (formerly a General Assurance) must indicate that status by checking the appropriate box in Item 4 on Form HHS 596 accompanying the application or the proposal. Within 30 days of the receipt of a written request from the Office for Protection from Research Risks (OPRR), the institution must submit the required assurances of compliance and certification of the IRB review and approval of the application or proposal.

3. RESTRICTION CODES are presented as a suffix to the Multiple Project Assurance "M" number. A restriction is based on the composition of the IRB(s) and indicates that additional expertise on the Institutional Review Board is necessary for particular activities requiring certification.

An XM suffix indicates that the IRB has an insufficient number of medical members. A proposed activity requiring medical expertise to assess risks, benefits, and the adequacy of safeguards cannot be certified under an XM restriction.

An XB suffix indicates that the IRB has an insufficient number of members expert in the behavioral sciences. A proposed activity requiring behavioral expertise to assess risks, benefits, and the adequacy of safeguards cannot be certified under an XB restriction.

FIGURE 31 (cont)

When an application or proposal comes within the scope of a restricted IRB, the IRB must add additional members to offset the restriction. Their names and qualifications must be reported to and approved by OPRR prior to the award of funds.

4. ALL QUESTIONS regarding the status of Multiple Project (formerly General) or Single Project (formerly Special) Assurances of Compliances and other matters concerning the protection of human subjects of research should be directed to:

The Office for Protection from Research Risks (OPRR) (301) 496-7041

5. FORMS

Bulk orders for additional copies of Form HHS 596 should be addressed to:

Office Service Section
Division of Research Grants
National Institutes of Health
Westwood Building, Room A-17
Bethesda, Maryland 20205

Single copies of Form HHS 596 can be obtained from OPRR.

Office for Protection
from Research Risks
9000 Rockville Pike
Building 31, Room 4B09
Bethesda, Maryland 20205

Charles R. McCarthy, Ph.D.
Director, Office for Protection
from Research Risks
Office of the Director
National Institutes of Health

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|--|---------------|
| <u>ALABAMA</u> | | |
| M1149 | Alabama, University of, Birmingham..... | Birmingham |
| M1074 | Alabama, University of..... | University |
| M1223 | South Alabama University of, including..... the Medical Center | Mobile |
| <u>ARIZONA</u> | | |
| M1108 | Arizona State University..... | Tempe |
| M1233 | Arizona, University of Hlth Sciences Ctr..... | Tucson |
| M1435-XB | St. Joseph's Hospital and Medical Center..... | Phoenix |
| <u>ARKANSAS</u> | | |
| M1451-XB | Arkansas, University of, Medical Center..... | Little Rock |
| <u>CALIFORNIA</u> | | |
| M1336-XM | American Institutes for Research in Behavioral Sciences | Palo Alto |
| M1329 | California Institute of Technology..... | Pasadena |
| M1400 | California State Health and Welfare..... (all Agency Departments) | Sacramento |
| M1349 | California, University of, Berkeley..... (incl The Laurence Berkeley Laboratories & The Donner Laboratories) | Berkeley |
| M1325 | California, University of, Davis..... | Davis |
| M1305 | California, University of, Irvine..... | Irvine |
| M1127 | California, University of, Los Angeles..... | Los Angeles |
| M1147 | California, University of, Riverside..... | Riverside |
| M1274 | California, University of, San Diego (incl... Veterans Administration Medical Center @ San Diego) | La Jolla |
| M1169 | California, University of, San Francisco..... (incl the Gladstone Foundation Laboratories for Cardiovascular Research) | San Francisco |

RESTRICTION CODES

XM -- No Medical or IND Studies

XB -- No Behavioral Studies

MARCH

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|--|-------------------------|
| M1244 | California, University of, Santa Barbara..... | Santa Barbara |
| M1205-XM | California, University of, Santa Cruz..... | Santa Cruz |
| M1157 | Cedars-Sinai Medical Center..... | Los Angeles |
| M1068 | Childrens Hospital Med. Ctr. of N. Calif..... | Oakland |
| M1118 | Children's Hospital of Los Angeles..... | Los Angeles |
| M1433-XB | Children's Hospital of San Francisco..... | San Francisco |
| M1043 | City of Hope National Medical Center,..... (incl. Beckman Research Institute) | Duarte |
| M1301 | Harbor-University of California, Los Angeles Medical Center | Torrance |
| M1306 | Institute for Medical Research (incl..... Santa Clara Valley Medical Center) | San Jose |
| M1312 | Kaiser Foundation Research Institute, Kaiser Foundation Hospitals in Oakland, Los Angeles, San Francisco (CA), Honolulu, Ohio Region, and the Kaiser Services Research Center in Portland, Oregon | Oakland |
| M1383 | La Jolla Cancer Research Foundation..... | La Jolla |
| M1415-XB | Lawrence Livermore National Laboratory..... | Livermore |
| M1295 | Loma Linda University (incl The Medical Ctr & Community Hosp).... | Loma Linda Riverside |
| M1372 | Los Angeles County-University..... of Southern California Medical Center, (incl the Schools of Medicine, Dentistry, Pharmacy and Nursing, and the Cancer Ctr, the Doheny , Eye Fnd, and the Campus Outpatient Facilities | Los Angeles |
| M1386 | Los Angeles County King/Drew Med Ctr incl.... the Medical Schools, the General Hospital and the Professional Staff Association Fdn | Los Angeles |
| M1373-XB | Memorial Hospital Medical Center/Long Beach.. | Long Beach |
| M1419 | Mental Research Institute..... | Palo Alto |
| M1293 | Mount Zion Hospital and Medical Center..... | San Francisco |
| M1380-XB | Northern California Cancer Program..... | Palo Alto |
| M1179 | Pacific Medical Center (includes..... Presbyterian Hospital, The University of the Pacific Dental School and The Medical Research Institute components as follows; | San Francisco |

RESTRICTION CODES

XM -- No Medical or IND Studies

XB -- No Behavioral Studies

MARCH 1985

FIGURE 31 (cont)

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|---|---------------|
| M1179 | Pacific Medical Center....(Continued) Heart Research Institute, Institute of Biomedical Engineering Sciences, Institute of Epidemiology and Behavioral Sciences, Institute of Cancer Research, Institute of Neurological Sciences, Kuzell Institute for Arthritis Research, Smith-Kettlewell Institute of Visual Sciences and the Smith- Kettlewell Eye Research Foundation | |
| M1005-XB | Palo Alto Medical Research Foundation..... | Palo Alto |
| M1114 | Rancho Los Amigos Hospital and..... Professional Staff Association | Downey |
| M1031 | Rand Corporation..... | Santa Monica |
| M1022 | Salk Institute..... | San Diego |
| M1436 | San Diego State University..... | San Diego |
| M1204-XM | San Francisco State University..... | San Francisco |
| M1165 | San Jose State University..... | San Jose |
| M1020-XM | Scientific Analysis Corporation (includ-.... ing the Institute for Scientific Analysis (and Performance Sites in Berkeley, San Francisco and Panorama City) | San Francisco |
| M1294-XB | Scripps Clinic and Research Foundation..... | La Jolla |
| M1299 | Southern California, University of..... (University Park campus) | Los Angeles |
| M1088 | SRI International..... | Menlo Park |
| M1272 | Stanford Univ (inc., Children's Hospital).... and the VA Medical Center at Palo Alto) | Stanford |
| M1292 | Veterans Administration Center..... | Sepulveda |
| M1163 | Veterans Administration Hospital..... | Long Beach |
| M1474 | Veterans Administration Medical Center..... | Martinez |
| M1087 | Veterans Administration Wadsworth..... Medical Center | Los Angeles |
| M1158-XM | Wright Institute..... | Berkeley |

COLORADO

| | | |
|----------|------------------------------------|--------------|
| M1224 | Children's Hospital of Denver..... | Denver |
| M1153 | Colorado State University..... | Fort Collins |
| M1144-XM | Colorado, University of..... | Boulder |

ND Studies
udies

MARCH 1985

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|--|--------|
| M1252 | Colorado, University of Health Sci Ctr..... | Denver |
| | (incl. VA Medical Center) | |
| M1410-XM | Denver, University of (incl.....) | Denver |
| | Denver Research Institute, Academic Research Center, and Colorado Seminary) | |
| M1009 | National Jewish Hosp/National Asthma Center.. | Denver |

CONNECTICUT

| | | |
|----------|--|------------|
| M1057 | Connecticut State Department of Health..... | Hartford |
| M1023 | Connecticut, University of..... | Storrs |
| M1345 | Connecticut, University of, Hlth Center..... | Farmington |
| M1070 | Connecticut Valley Hospital..... | Middletown |
| M1421-XB | Hartford Hospital..... | Hartford |
| M1452 | Haskins Laboratories..... | New Haven |
| M1094 | Institute of Living..... | Hartford |
| M1452 | John B. Pierce Fdn of Connecticut, Inc..... | New Haven |
| M1470 | Newington Children's Hospital..... | Newington |
| M1276 | Saint Francis Hospital & Medical Ctr..... | Hartford |
| M1437 | Waterbury Hospital..... | Waterbury |
| M1452 | Yale University..... | New Haven |

DELAWARE

| | | |
|-------|-------------------------------------|------------|
| M1360 | Delaware, University of..... | Newark |
| M1366 | Wilmington Medical Center, Inc..... | Wilmington |

DISTRICT OF COLUMBIA

| | | |
|----------|--|------------|
| M1336-XM | American Institutes for Research in the..... | Washington |
| | Behavioral Sciences (incl sites in Washington, D.C., Palo Alto, Ca., Cambridge, Ma., and Bedford, Ma.) | |
| M1228-XB | American National Red Cross..... | Washington |
| M1086-XM | Bureau of Social Science Research, Inc..... | Washington |
| M1066-XM | Catholic University of America..... | Washington |
| M1316 | - Children's Hospital National Medical Ctr..... | Washington |

RESTRICTION CODES

XM -- No Medical or IND Studies
 XB -- No Behavioral Studies

MARCH 1985

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|--|------------|
| M1318-XM | Gallaudet College..... | Washington |
| M1125 | George Washington University..... | Washington |
| M1255 | Georgetown University..... | Washington |
| M1469 | Gorgas Memorial Institute of..... | Washington |
| | Tropical & Preventative Medicine, Inc | |
| M1102 | Howard University..... | Washington |
| M1219 | National Academy of Sciences, including..... | Washington |
| | National Academy of Engineering, | |
| | Institute of Medicine, and National | |
| | Research Council | |
| M1408 | Veterans Administration Medical Center..... | Washington |
| M1454-XB | Washington Hospital Center..... | Washington |

FLORIDA

| | | |
|----------|---|--------------|
| M1350 | Florida State Department of Health and..... | Tallahassee |
| | Rehabilitative Services | |
| M1339-XM | Florida State University..... | Tallahassee |
| M1266 | Florida, University of..... | Gainesville |
| M1101-XB | Miami Heart Institute..... | Miami Beach |
| M1196 | Miami, University of..... | Coral Gables |
| M1196 | Miami, University of..... | Miami |
| M1124-XB | Mt Sinai Medical Center of Greater Miami..... | Miami Beach |
| M1196 | Papanicolaou Cancer Research Institute..... | Miami |
| M1284 | South Florida, University of..... | Tampa |
| M1196 | Veterans Administration Medical Center..... | Miami |

GEORGIA

| | | |
|----------|--|---------|
| M1141 | Centers for Disease Control, PHS..... | Atlanta |
| M1346-XM | Emory Univ Graduate Sch of Arts and Sci..... | Atlanta |
| M1427-XM | Emory Univ Nell Hodgson Woodruff School..... | Atlanta |
| | of Nursing | |
| M1425-XB | Emory Univ School of Dentistry..... | Atlanta |
| M1426 | Emory Univ School of Medicine..... | Atlanta |
| M1026 | Georgia Dept of Human Resources,..... | Atlanta |
| | All Units | |

RESTRICTION CODES

XM -- No Medical or IND Studies
 XB -- No Behavioral Studies

MARCH 1985

FIGURE 31 (cont)

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|---|----------|
| M1395 | Georgia Institute of Technology,..... | Atlanta |
| | including Engineering Experiment Station, and Georgia Tech Research Institute | |
| M1112 | Georgia, Medical College of..... | Augusta |
| M1047-XM | Georgia, University of, and Research..... | Athens |
| | Foundation | |
| M1220-XB | Natl. Inst for Occupational Safety & Hlth.... | Atlanta |
| M1461-XB | University Hospital..... | Augusta |
| <u>HAWAII</u> | | |
| M1217 | Hawaii, University of, at Manoa..... | Honolulu |
| M1312 | Kaiser Foundation Hospitals (In all..... | Honolulu |
| | regions plus the Kaiser Foundation Research Institute: see California | |
| <u>IDAHO</u> | | |
| M1247-XB | Mountain States Tumor Institute..... | Boise |
| <u>ILLINOIS</u> | | |
| M1365 | American Dental Assn and ADA Health Fdn..... | Chicago |
| M1321-XM | Anna Mental Health and Developmental Ctr..... | Anna |
| M1264 | Chicago, University of (Division of | Chicago |
| | Biological Sciences and Pritzker Sch of Medicine, Division of Social Sci, Sch of Social Service Administration, and Related Units) | |
| M1245 | Children's Memorial Hospital..... | Chicago |
| M1236 | Downey Veterans Administration Hospital,.... | Downey |
| M1472 | Edward Hines Jr. VA Hospital..... | Hines |
| M1396 | Evanston Hospital..... | Evanston |
| M1236 | Hlth Sci, Univ of/Chicago Medical Sch..... | Chicago |
| M1150 | Hektoen Institute for Medical Research..... | Chicago |
| M1364 | Illinois Cancer Council..... | Chicago |

RESTRICTION CODES

XM -- No Medical or IND Studies
 XB -- No Behavioral Studies

MARCH 1985

FIGURE 31 (cont)

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|---|--------------|
| M1279 | Illinois State Psychiatric Institute..... | Chicago |
| M1095 | Illinois, University of, at Chicago..... | Chicago |
| M1095 | Illinois, University of, Medical Center..... | Chicago |
| | Campus, including Rockford School of Medicine, and Peoria School of Medicine | |
| M1004 | Illinois, Univ of, and all components..... | Urbana |
| | at Urbana-Champaign | |
| M1387 | Loyola University Medical Center..... | Maywood |
| M1014 | Michael Reese Hospital and Medical Ctr..... | Chicago |
| M1367 | Mount Sinai Hospital Medical Center..... | Chicago |
| | of Chicago | |
| M1413 | Northern Illinois University..... | DeKalb |
| M1319 | Northwestern Medical Faculty Foundation..... | |
| | Northwestern Memorial Hospital..... | Chicago |
| | Northwestern University..... | Chicago |
| | Northwestern University..... | Evanston |
| M1319 | Rehabilitation Institute of Chicago..... | Chicago |
| M1385 | Rush-Presbyterian-St Luke's Medical Ctr..... | Chicago |
| M1042 | Southern Illinois University..... | Carbondale |
| M1137 | Southern Illinois University..... | Edwardsville |
| M1311 | Southern Illinois Univ Sch of Medicine..... | Springfield |
| M1319 | VA Lakeside Hospital of Chicago..... | Chicago |
| M1173 | Western Illinois University..... | Macomb |

INDIANA

| | | |
|----------|--|----------------|
| M1028 | Fort Wayne State Hosp and Training Ctr..... | Ft Wayne |
| M1167 | Indiana Univ and Indiana Univ Foundation..... | Bloomington |
| | | Indianapolis |
| M1167 | Indiana Univ-Purdue Univ (Med Facility)..... | Indianapolis |
| I1167 | Indiana University Regional Campuses at Fort Wayne, Gary, Kokomo, New Albany, and South Bend | |
| M1167 | Indianapolis Center for Advanced Research.... | Indianapolis |
| M1342-XB | Methodist Hospital of Indiana, Inc..... | Indianapolis |
| M1262-XM | Notre Dame, University of..... | Notre Dame |
| M1162 | Purdue Univ and Purdue Research Fdn..... | West Lafayette |

RESTRICTION CODES

XM -- No Medical or IND Studies
 XB -- No Behavioral Studies

MARCH 1985

FIGURE 31 (cont)

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

ASSURANCE

NUMBER

STATE/INSTITUTION

CITY

IOWA

M1361-XM Iowa State Univ of Science and Technology....Ames
 M1080 Iowa, University of.....Iowa City

KANSAS

M1296 Kansas State University.....Manhattan
 M1234 Kansas, University of - Lawrence Campus.....Lawrence
 M1122 Kansas, University of,.....Kansas City
 College of Health Sciences and Hospital
 M1432 Menninger Foundation.....Topeka
 M1051 Midwest Research Institute.....Kansas City
 M1096-XB VA Medical Center.....Kansas City

KENTUCKY

M1324 Kentucky, Univ of, and the Research Fdn.....Lexington
 M1189 Louisville, University of, & Humana Hospital.University
 M1324 Veterans Administration Hospital.....Lexington

LOUISIANA

M1046 Alton Ochsner Medical Foundation.....New Orleans
 M1128 Louisiana State Univ and A & M College.....Baton Rouge
 M1129-XM Louisiana State Univ in Baton Rouge.....Baton Rouge
 M1130 Louisiana State Univ Medical Center.....New Orleans
 M1131 Louisiana State Univ Medical Center.....Shreveport
 M1132-XM Louisiana State UnivAlexandria
 M1133-XM Louisiana State Univ.....Eunice
 M1134-XM Louisiana State Univ of, Shreveport.....Shreveport
 M1135-XM Louisiana State Univ.....New Orleans

RESTRICTION CODES

-- No Medical or IND Studies
 -- No Behavioral Studies

MARCH 1985

FIGURE 31 (cont)

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|--|--------------|
| M1039-XM | Pinecrest State School..... | Pineville |
| M1260-XB | Tulane Medical Center..... | New Orleans |
| M1267-XM | Tulane University, except Medical Center..... | New Orleans |
| <u>MAINE</u> | | |
| M1148 | Aroostook Medical Center..... | Presque Isle |
| M1353 | Eastern Maine Medical Center..... | Bangor |
| M1197 | Maine Medical Center..... | Portland |
| <u>MARYLAND</u> | | |
| M1140 | Francis Scott Key Medical Center..... | Baltimore |
| M1222-XB | Frederick Cancer Research Center..... | Frederick |
| M1175 | Friends Medical Science Research Ctr Inc..... | Baltimore |
| M1015 | John F. Kennedy Institute for..... Handicapped Children | Baltimore |
| M1091-XM | Johns Hopkins University Faculty of Arts..... and Sciences | Baltimore |
| M1090 | Johns Hopkins Univ School of Hygiene and..... Public Health | Baltimore |
| M1011 | Johns Hopkins Univ School of Medicine and..... Johns Hopkins Hospital | Baltimore |
| M1174 | Maryland, Univ of, at Baltimore..... | Baltimore |
| M1265-XM | Maryland, Univ of, Baltimore Cnty..... | Catonsville |
| M1362-XM | Maryland, Univ of, at College Park..... | College Park |
| M1000 | NIH, Clinical Center, all Institutes & Units..... | Bethesda |
| M1338 | Sinai Hospital of Baltimore, Inc..... | Baltimore |
| M1459-XM | Survey Research Associate Inc..... | Baltimore |
| M1441 | U.S. Food & Drug Administration/PHS/HHS..... | Rockville |

RESTRICTION CODES

XM -- No Medical or IND Studies
 XB -- No Behavioral Studies

MARCH 198

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|----------------------|---|---------------|
| <u>MASSACHUSETTS</u> | | |
| M1336-XM | American Institutes for Research in..... | Bedford |
| | the Behavioral Sciences | |
| M1336-XM | American Institutes for Research in..... | Cambridge |
| | the Behavioral Sciences | |
| M1310 | Beth Israel Hospital..... | Boston |
| M1409 | Boston City Hospital..... | Boston |
| M1428-XM | Boston Univ, Charles River Campus..... | Boston |
| M1290-XB | Boston Univ Medical Center..... | Boston |
| M1290-XB | Boston Univ School of Graduate Dentistry..... | Boston |
| M1290-XB | Boston Univ School of Medicine (incl..... | Boston |
| | School of Public Health) | |
| M1416-XM | Brandeis University..... | Waltham |
| M1049 | Brigham and Women's Hospital..... | Boston |
| M1271-XB | Center for Blood Research, Inc..... | Boston |
| M1443-XM | Clark University..... | Worcester |
| M1034-XB | Dana Farber Cancer Institute, Inc..... | Boston |
| M1378 | Eunice Kennedy Shriver Ctr f/Mnt Retard Inc.. | Waltham |
| M1352-XB | Eye Research Institute of Retina Fnd..... | Boston |
| M1024-XB | Forsyth Dental Center..... | Boston |
| M1240 | Harvard Medical School..... | Boston |
| M1240 | Harvard School of Dental Medicine..... | Boston |
| M1084 | Harvard Univ, Faculty of Arts and Sci..... | Cambridge |
| M1093-XM | Harvard Univ, Graduate Sch of Education..... | Cambridge |
| M1208 | Harvard Univ, School of Public Health..... | Boston |
| M1286 | Joslin Diabetes Center..... | Boston |
| M1288-XB | Lahey Clinic Foundation, Inc..... | Boston |
| M1417-XB | Lemuel Shattuck Hospital..... | Jamaica Plain |
| M1409 | Long Island Hospital..... | Boston |
| M1243 | Mass Dept of Mental Health..... | Boston |
| M1354-XB | Massachusetts Eye and Ear Infirmary..... | Boston |
| M1331 | Massachusetts General Hospital..... | Boston |
| M1377 | Massachusetts Institute of Technology..... | Cambridge |
| M1431 | Massachusetts Mental Health Center..... | Boston |
| M1431 | Massachusetts Mental Health Research Corp.... | Boston |
| M1003 | Massachusetts, University of - Amherst..... | Amherst |
| M1207 | Massachusetts, University of, Med Sch..... | Worcester |
| M1409 | Mattapan Hospital..... | Mattapan |
| M1287 | McLean Hospital Corporation..... | Belmont |

RESTRICTION CODES

XM -- No Medical or IND Studies

XB -- No Behavioral Studies

MARCH 1985

FIGURE 31 (cont)

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|---|------------|
| M1429 | Mount Auburn Hospital..... | Cambridge |
| M1289-XB | New England Deaconess Hospital..... | Boston |
| M1440 | New England Medical Center Hospital..... | Boston |
| M1298 | North Charles Mental Health Research &..... Training Foundation, Inc | Cambridge |
| M1275 | Northeastern University..... | Boston |
| M1460 | St. Elizabeth's Hospital of Boston..... | Boston |
| M1176-XB | St Margaret's Hospital for Women..... | Boston |
| M1273 | The Children's Hospital Corporation, Inc..... | Boston |
| M1409 | Trustees of Hlth & Hosps, Cty of Boston.Inc.. (Boston City, Hosp., Long Island Hosp., Mattapan Hosp., Dorchester House Neighborhood Hlth Ctr., Whittier St Neighborhood Hlth Ctr., Harvard St Neighborhood Hlth Ctr., East Boston Neighborhood Hlth Ctr., South Boston Neighborhood Hlth Cr., & Uphams Corner Hlth Center) | Boston |
| M1439 | Tufts-New England Medical Center..... | Boston |
| M1438 | Tufts University - Boston..... | Boston |
| M1328 | Tufts University - Medford..... | Medford |
| M1290-XB | University Hospital, Inc..... | Boston |
| M1378 | Walter E. Fernald State School..... | Belmont |
| M1190-XB | Worcester City Hospital..... | Worcester |
| M1229 | Worcester Foundation for Experimental..... Biology | Shrewsbury |

MICHIGAN

| | | |
|----------|---|---------|
| M1232 | Children's Hospital of Michigan..... | Detroit |
| M1340 | Detroit, University of..... | Detroit |
| M1191 | Edsel B. Ford Institute for Med Research..... | Detroit |
| M1191 | Henry Ford Hospital..... | Detroit |
| M1235 | Lafayette Clinic..... | Detroit |
| M1341-XB | Michigan Cancer Foundation..... | Detroit |
| M1320 | Michigan Department of Public Health..... | Lansing |

RESTRICTION CODES

XM -- No Medical or IND Studies

XB -- No Behavioral Studies

MARCH 1985

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|---|--------------|
| M1239 | Michigan State University..... | East Lansing |
| M1184 | Michigan, University of..... | Ann Arbor |
| M1184 | Michigan, University of..... | Dearborn |
| M1184 | Michigan, University of..... | Flint |
| M1071 | Oakland University..... | Rochester |
| M1201 | Veterans Administration Med Ctr-Ann Arbor.... | Ann Arbor |
| M1261 | Wayne State University..... | Detroit |
| M1192-XM | Western Michigan University..... | Kalamazoo |

MINNESOTA

| | | |
|----------|---|-------------|
| M1154-XB | Hennepin County Medical Center..... | Minneapolis |
| M1006 | Mayo Foundation and Mayo Clinic..... | Rochester |
| M1154-XB | Minneapolis Medical Research Fdn, Inc..... | Minneapolis |
| M1337 | Minnesota, University of, Hormel Institute... | Austin |
| M1337 | Minnesota, University of,..... | Crookston |
| M1337 | Minnesota, University of..... | Duluth |
| M1337 | Minnesota, University of..... | Minneapolis |
| M1337 | Minnesota, University of..... | Morris |
| M1337 | Minnesota, University of..... | St Paul |
| M1337 | Minnesota, University of,..... | Waseca |
| M1337 | Minnesota, University of Hospital & Med Ctr.. | Minneapolis |
| M1160-XB | Veterans Administration Medical Center..... | Minneapolis |

MISSISSIPPI

| | | |
|----------|---|------------|
| M1237-XM | Mississippi, University of (Main Campus)..... | University |
| M1045 | Mississippi, University of, Medical Ctr..... | Jackson |

MISSOURI

| | | |
|----------|--|-------------|
| M1168-XM | American Nurses' Association, Inc..... | Kansas City |
| M1053 | Ellis Fischel State Cancer Ctr (incl..... Cancer Research Center) | Columbia |
| M1382 | Jewish Hospital of St Louis..... | St Louis |

RESTRICTION CODES

XM -- No Medical or IND Studies
 XB -- No Behavioral Studies

MARCH 1985

FIGURE 31 (cont)

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|--|-------------|
| M1412-XB | Kirkville Coll of Osteopathic Medicine..... | Kirkville |
| M1051 | Midwest Research Institute..... | Kansas City |
| M1017 | Missouri, University of..... | Columbia |
| M1017 | Missouri, University of..... | Kansas City |
| M1119 | St Louis University Medical Center..... | St Louis |
| M1096-XB | Veterans Admin Medical Center..... | Kansas City |
| M1397-XM | Washington University (excluding Sch of Medicine and Dentistry) | St Louis |
| M1123 | Washington University School of Medicine..... | St Louis |

NEBRASKA

| | | |
|-------|--|-----------|
| M1117 | Creighton University..... | Omaha |
| M1218 | Father Flanagan's Boys' Home..... | Boys Town |
| M1317 | Nebraska, Univ of, incl Medical Ctr & University Hospital | Omaha |
| M1317 | Nebraska, Univ of,..... | Lincoln |

NEVADA

| | | |
|-------|--|------|
| M1164 | Nevada, University of, Reno Campus..... (includes all components of the Univ, Reno Campus) | Reno |
|-------|--|------|

NEW HAMPSHIRE

| | | |
|----------|--|---------|
| M1379-XM | Dartmouth College (Arts & Sciences)..... | Hanover |
| M1048 | Dartmouth Medical School..... | Hanover |
| M1278 | New Hampshire, University of..... | Durham |

NEW JERSEY

| | | |
|----------|--|-----------|
| M1466 | Center for Molecular Medicine and Immunology | Newark |
| M1418-XM | Educational Testing Service..... | Princeton |

RESTRICTION CODES

XM -- No Medical or IND Studies
 XB -- No Behavioral Studies

MARCH 1985

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|---|---------------|
| M1069-XB | Institute for Medical Research..... | Camden |
| M1202 | Newark Beth Israel Medical Center..... | Newark |
| M1002-XM | Princeton University..... | Princeton |
| M1370 | Rutgers, The State Univ of New Jersey..... | Camden |
| M1370 | Rutgers, The State Univ of New Jersey..... | New Brunswick |
| M1370 | Rutgers, The State Univ of New Jersey..... | Newark |
| M1465 | UMDNJ-New Jersey Dental School..... | Newark |
| M1466 | UMDNJ-New Jersey Medical School..... | Newark |
| M1464 | UMDNJ-New Jersey School of Osteopathic..... | Piscataway |
| | Medicine | |
| M1467 | UMDNJ-Rutgers Medical School..... | Piscataway |

NEW MEXICO

| | | |
|----------|---|-------------|
| M1330-XM | New Mexico, University of..... | Albuquerque |
| M1450 | New Mexico, University of, Medical Center.... | Albuquerque |

NEW YORK

| | | |
|----------|--|-------------|
| M1187 | Agricultural and Technical Coll., SUNY..... | Farmingdale |
| M1121 | Albany Medical College of Union Univ (incl... VA Medical Center) | Albany |
| M1193 | American Health Foundation..... | New York |
| M1313-XB | Associated Universities, Inc, including..... Brookhaven National Laboratory, and Hospital of the Medical Research Center) | Upton |
| M1381 | Beth Israel Medical Center, also..... Hospital for Joint Diseases and the Orthopedic Institute. | New York |
| M1374-XM | Canisius College..... | Buffalo |
| M1199-XM | Center for Policy Research, Inc..... | New York |
| M1314 | Children's Hospital of Buffalo..... | Buffalo |
| M1356-XB | Columbia Presbyterian Medical Center (incl... Presbyterian Hospital & the Health Sciences Division of Columbia University) | New York |
| M1309-XM | Columbia Univ, except Hlth Sci Division..... | New York |

RESTRICTION CODES

XM -- No Medical or IND Studies

XB -- No Behavioral Studies

MARCH 1985

FIGURE 31 (cont)

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|---|------------------|
| M1393-XM | Columbia University, Teacher's College..... | New York |
| M1269 | Cornell Univ, (except Univ Medical Ctr)..... | Ithaca |
| M1185 | Cornell University Medical Center (incls..... Medical College, N.Y. Hospital and Cornell University Graduate School of Medical Sciences) | New York |
| M1178-XB | Eastman Dental Center..... | Rochester |
| M1142-XM | Empire State College SUNY..... | Saratoga Springs |
| M1463-XM | Fordham University..... | Bronx |
| M1058 | Genesee Hospital..... | Rochester |
| M1037 | Health Research, Inc, Roswell Park Div..... | Buffalo |
| M1109 | Hospital for Special Surgery..... | New York |
| M1351 | Jewish Board of Family and Children's..... Services, Inc | New York |
| M1007 | Kingsbrook Jewish Medical Center and..... Isaac Albert Research Institute | Brooklyn |
| M1097 | Long Island Jewish-Hillside Medical Ctr..... | New Hyde Park |
| M1333-XB | Maimonides Medical Center and Coney..... Island Hospital (Associated Institutions) | Brooklyn |
| M1151 | Mary Imogene Bassett Hospital..... | Cooperstown |
| M1210 | Memorial Sloan Kettering Cancer Center..... | New York |
| M1062 | Montefiore Hospital and Medical Center..... | Bronx |
| M1155 | Mount Sinai School of Medicine of CUNY..... | New York |
| M1055 | Nassau County Medical Center, including..... Meadowbrook Medical Education and Research Foundation, Inc | East Meadow |
| M1445-XM | New School for Social Research..... | New York |
| M1052-XB | New York Blood Center, Inc..... | New York |
| M1111-XM | New York, City Univ of, Bernard Baruch Coll.. | New York |
| M1111-XM | New York, City Univ of, Borough of..... Manhattan Community College | New York |
| M1111-XM | New York, City Univ of, Bronx Cmty Coll..... | Bronx |
| M1111-XM | New York, City Univ of, Brooklyn College..... | Brooklyn |
| M1111-XM | New York, City Univ of, City College..... | New York |
| M1111-XM | New York, City Univ of, College of..... Staten Island | Staten Island |
| M1111-XM | New York, City Univ of, Graduate School..... and University Center | New York |
| M1111-XM | - New York, City Univ of, Herbert H..... Lehman College | Bronx |

RESTRICTION CODES

XM -- No Medical or IND Studies

XB -- No Behavioral Studies

MARCH 1985

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|--|-------------|
| M1111-XM | New York, City Univ of, Hostos Cmty College.. | Bronx |
| M1111-XM | New York, City Univ of, Hunter College..... | New York |
| M1111-XM | New York, City Univ of, John Jay College..... | New York |
| | of Criminal Justice | |
| M1111-XM | New York, City Univ of, Kingsborough..... | Brooklyn |
| M1111-XM | New York, City Univ of, LaGuardia Cmty Coll.. | Queens |
| M1111-XM | New York, City Univ of, Medgar Evers Coll.... | Brooklyn |
| M1111-XM | New York, City Univ of, New York City..... | Brooklyn |
| | Technical College | |
| M1111-XM | New York, City Univ of, Queens College..... | Flushing |
| M1111-XM | New York, City Univ of, Queensborough..... | New York |
| | Community College | |
| M1111-XM | New York, City Univ of, Research Fdn..... | New York |
| M1111-XM | New York, City Univ of, York College..... | Jamaica |
| M1241-XB | New York State Department of, Hlth (exclus...) | Albany |
| | (of Roswell Park Memorial Institute) | |
| M1376 | New York State Dept of Mental Hlth (incls...) | Albany |
| | (Research Foundation for Mental Hygiene, Inc | |
| | with some 40 different sites-call the | |
| | Regional coordinator) | |
| M1327 | New York Medical College (Graduate.....) | Valhalla |
| | School of Medical Sciences, Graduate | |
| | School of Hlth Sciences & Medical School) | |
| M1449-XM | New York, State Univ of, at Albany (incl....) | Albany |
| | Research Foundation of SUNY) | |
| M1209 | New York, State Univ of, at Binghamton..... | Binghamton |
| M1270 | New York, State Univ of, at Buffalo..... | Buffalo |
| M1326-XM | New York, State Univ of, | Geneseo |
| M1036 | New York, State Univ of, at Stony Brook..... | Stony Brook |
| M1064-XM | New York, State Univ of, College at..... | Brockport |
| | Brockport | |
| M1420-XM | New York, State Univ of, Coll at Buffalo..... | Buffalo |
| M1010-XM | New York, State Univ of, Coll at Cortland.... | Cortland |
| M1242 | New York, State Univ of, Coll of Optometry... | New York |
| M1181-XM | State University College..... | Oneonta |
| M1430-XM | New York, State Univ of, Coll at Oswego..... | Oswego |

RESTRICTION CODES

XM -- No Medical or IND Studies

XB -- No Behavioral Studies

MARCH 1985

FIGURE 31 (cont)

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|--|------|
| M1073 | New York, State Univ of, Downstate Med.Ctr...Brooklyn and State University Hospital | |
| M1303 | New York, State Univ of, Upstate Med Ctr.....Syracuse | |
| M1250 | New York Univ, exclusive of the Med Ctr.....New York | |
| M1177 | New York University Medical Center (incl.....New York School of Medicine, Post Graduate Med Sch University Hospital, the Institute of Rehabilitation Med and Center Admin) | |
| M1302 | North Shore University Hospital.....Manhasset | |
| M1300 | Rensselaer Polytechnic Institute.....Troy | |
| M1111-XM | Research Fdn of the City Univ of New York....New York | |
| M1357 | Rochester, University of (includes.....Rochester School of Medicine & Dentistry, School of Nursing, Strong Memorial Hospital, Center for Naval Analysis, College of Arts & Sciences, Graduate School of Education & Human Development and the College of Engineering & Applied Science) | |
| M1297 | Rockefeller University.....New York | |
| M1037 | Roswell Park Memorial Institute.....Buffalo | |
| M1083 | St. Johns University.....Jamaica | |
| M1253 | St Luke's Roosevelt Institute for Hlth Sci...New York (includes St. Lukes-Roosevelt Hospital Center) | |
| M1277-XB | St Mary's Hospital.....Rochester | |
| M1227 | St Vincent's Hosp & Med Ctr of New York.....New York | |
| M1054-XM | Syracuse University.....Syracuse | |
| M1254-XB | Trudeau Institute.....Saranac Lake | |
| M1444 | Veterans Administration Hospital.....Northport | |
| M1063-XB | Yeshiva Univ, Albert Einstein Coll of Med....Bronx | |

NORTH CAROLINA

| | | |
|----------|---|-------------|
| M1106 | Duke University Medical Center | Durham |
| M1414-XM | Duke University exclusive of the..... | Durham |
| | Medical Center | |
| M1389 | North Carolina A & T State University..... | Greensboro |
| M1263 | North Carolina State University at Raleigh... | Raleigh |
| M1390 | North Carolina, Univ of, at Chapel Hill..... | Chapel Hill |

RESTRICTION CODES

XM -- No Medical or IND Studies

XB -- No Behavioral Studies

MARCH 1985

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|---|---------------|
| M1161-XB | Wake Forest Univ, Bowman Gray Sch of Med..... | Winston-Salem |
| M1335-XM | Wake Forest Univ, Except Sch of Medicine..... | Winston-Salem |
| M1391 | Western Carolina Center..... | Morganton |

OHIO

| | | |
|----------|---|------------------|
| M1159 | Akron General Medical Center..... | Akron |
| M1077 | Akron, University of..... | Akron |
| M1221 | Battelle Columbus Laboratories of the..... Battelle Memorial Institute | Columbus |
| M1186 | Bowling Green State University..... | Bowling Green |
| M1258 | Case Western Reserve University..... | Cleveland |
| M1170 | Children's Hospital Medical Center..... | Cincinnati |
| M1424 | Children's Hospital Research Fdn, Inc..... | Columbus |
| M1138 | Cincinnati, Univ of, incl., Medical Ctr..... | Cincinnati |
| M1388-XB | Cleveland Clinic Foundation and..... Cleveland Clinic Educational Foundation | Cleveland |
| M1280 | Cleveland Psychiatric Institute..... | Cleveland |
| M1021 | Cox Heart Institute..... | Dayton |
| M1021 | Fels Research Institute..... | Yellow Springs |
| M1107 | Jewish Hospital of Cincinnati, including..... the School of Nursing, Children's Psychiatric Center, and May Institute for Medical Research | Cincinnati |
| M1282-XM | Kent State University..... | Kent |
| M1166-XB | Marymount Hospital..... | Garfield Heights |
| M1358 | Medical College of Ohio at Toledo..... | Toledo |
| M1104 | Mount Sinai Medical Center..... | Cleveland |
| M1238 | Ohio State University and Research Fdn..... | Columbus |
| M1203 | St Luke's Hospital..... | Cleveland |
| M1398 | University Hospitals of Cleveland..... | Cleveland |
| M1021 | Wright State University (All Components)..... | Dayton |

OKLAHOMA

| | | |
|----------|---|---------------|
| M1092-XB | Oklahoma Medical Research Foundation, Inc.... | Oklahoma City |
| M1146 | - Oklahoma, University of..... | Norman |
| M1448 | Oklahoma, Univ of, Health Sciences Ctr..... (includes 25 affiliated institutions in 5 other cities-call Regional Coordinator) | Oklahoma City |

RESTRICTION CODES

XM -- No Medical or IND Studies
 XB -- No Behavioral Studies

MARCH 1985

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|---|--------------|
| <u>OREGON</u> | | |
| M1447-XM | Evaluation Research Group..... | Eugene |
| M1072 | Good Samaritan Hospital and Medical Ctr..... | Portland |
| M1312 | Kaiser Foundation Hospital..... | Portland |
| M1323-XB | Medical Research Foundation of Oregon &..... | Portland |
| | Oregon Regional Primate Research Ctr | |
| M1211-XM | Northwest Regional Educational Laboratory.... | Portland |
| M1215-XM | Oregon Research Institute..... | Eugene |
| M1099-XM | Oregon State University..... | Corvallis |
| M1143-XM | Oregon, University of..... | Eugene |
| M1359-XB | Oregon, Univ of, Hlth Sciences Center,..... | Portland |
| | including Schools of Medicine, Dentistry, and Nursing | |
| <u>PENNSYLVANIA</u> | | |
| M1212-XB | Albert Einstein Med Ctr, Northern Div..... | Philadelphia |
| M1050-XB | Allegheny Hlth, Education and Research..... | Pittsburgh |
| | Corporation - Allegheny-Singer Research Corporation & Allegheny General Hospital | |
| M1225 | Arthur P. Noyes Research Foundation..... | Norristown |
| M1462 | Carnegie-Mellon University..... | Pittsburgh |
| M1257-XB | Children's Hospital of Philadelphia..... | Philadelphia |
| | (Joseph Stokes, Jr., Research Inst of) | |
| M1230 | Children's Hospital of Pittsburgh..... | Pittsburgh |
| M1030 | Fox Chase Cancer Center (Institute for..... | Philadelphia |
| | Cancer Research & American Oncologic Hospital) | |
| M1100-XB | Franklin Institute..... | Philadelphia |
| M1156-XB | Geisinger Medical Center, Institute for..... | Danville |
| | Medical Education and Research | |

RESTRICTION CODES

XM -- No Medical or IND Studies

XB -- No Behavioral Studies

MARCH 1985

FIGURE 31 (cont)

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|--|-----------------|
| M1016-XB | Graduate Hospital, The..... | Philadelphia |
| M1116-XB | Hahnemann Medical College and Hospital..... | Philadelphia |
| M1038 | H. K. Cooper Institute for Oral-Facial..... | Lancaster |
| | Anomalies and Communicative Disorders (Lancaster Cleft Palate Clinic) | |
| M1226-XB | Lankenau Hospital..... | Philadelphia |
| M1399-XB | Magee-Womens Hospital..... | Pittsburgh |
| M1025 | Marriage Council of Philadelphia, Inc..... | Philadelphia |
| M1025 | Monell Chemical Senses Center..... | Philadelphia |
| M1402-XB | Montefiore Hospital..... | Pittsburgh |
| M1225 | Norristown State Hospital..... | Norristown |
| M1113 | Pennsylvania Hospital..... | Philadelphia |
| M1139 | Pennsylvania, Medical College of..... | Philadelphia |
| M1145 | Pennsylvania State University..... | University Park |
| M1027 | Penn State University Milton S. Hershey..... | Hershey |
| | Medical Center | |
| M1200-XB | Pennsylvania College of Podiatric Med..... | Philadelphia |
| M1025 | Pennsylvania, University of..... | Philadelphia |
| M1401-XB | Philadelphia Coll of Osteopathic Med..... | Philadelphia |
| M1029 | Philadelphia Department of Public Hlth..... | Philadelphia |
| M1322 | Philadelphia Geriatric Center..... | Philadelphia |
| M1446 | Philadelphia Psychiatric Center..... | Philadelphia |
| M1259 | Pittsburgh, University of..... | Pittsburgh |
| M1259 | Presbyterian-University Hospital..... | Pittsburgh |
| M1103 | Presbyterian-Univ of Penn Medical Center..... | Philadelphia |
| M1001-XB | St Joseph's Hospital..... | Lancaster |
| M1422-XM | Temple Univ excluding Hlth Sci Ctr..... | Philadelphia |
| M1442 | Temple University Hlth Sciences Center..... | Philadelphia |
| | including St. Christopher's Hospital for Children | |
| M1115 | Thomas Jefferson Univ (All Components)..... | Philadelphia |
| M1231-XB | Wills Eye Hosp and Research Institute..... | Philadelphia |
| M1347-XB | Wistar Institute..... | Philadelphia |

RESTRICTION CODES

XM -- No Medical or IND Studies

XB -- No Behavioral Studies

MARCH 1985

FIGURE 31 (cont)

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|-----------------------|---|-------------------------|
| <u>PUERTO RICO</u> | | |
| M1035-XM | Catholic University of Puerto Rico..... | Ponce |
| M1291-XB | Puerto Rico, Univ of, Med Sciences Campus.... | San Juan Rio Piedras |
| <u>RHODE ISLAND</u> | | |
| M1411 | Brown University..... | Providence |
| M1126-XM | Memorial Hospital..... | Pawtucket |
| M1307 | Rhode Island Hospital..... | Providence |
| M1457 | Rhode Island, University of..... | Kingston |
| M1041-XB | Roger Williams General Hospital..... | Providence |
| <u>SOUTH CAROLINA</u> | | |
| M1368-XM | Clemson University..... | Clemson |
| M1075 | South Carolina Dept of Hlth & Env Control.... | Columbia |
| M1281 | South Carolina Dept of Mental Health..... | Columbia |
| M1012-XB | South Carolina, Medical University of..... | Charleston |
| M1180 | South Carolina, University of..... | Columbia |
| <u>SOUTH DAKOTA</u> | | |
| M1206 | South Dakota, Univ of..... | Vermillion |
| <u>TENNESSEE</u> | | |
| M1194 | East Tennessee State University..... | Johnson City |
| M1384 | Meharry Medical College..... | Nashville |
| M1394 | Oak Ridge Associated Universities..... | Oak Ridge |
| M1394 | Oak Ridge National Laboratory..... | Oak Ridge |
| M1013 | St Jude Children's Research Hospital..... | Memphis |
| M1249-XM | Tennessee State University..... | Nashville |
| M1268-XM | Tennessee, University of..... | Chattanooga |
| M1056 | Tennessee, University of, Center for the..... | Memphis |
| | - Health Sciences | |
| M1081 | Tennessee, University of - Knoxville..... | Knoxville |
| M1363 | Vanderbilt University, also..... | Nashville |
| | George Peabody College for Teachers | |

RESTRICTION CODES

XM -- No Medical or IND Studies

XB -- No Behavioral Studies

MARCH 1985

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|--|-----------------|
| <u>TEXAS</u> | | |
| M1453 | Baylor, College of Dentistry..... | Dallas |
| M1060 | Baylor College of Medicine..... | Houston |
| M1067-XM | Houston, University of..... (AKA Southwest Educ Develpment Lab) | Houston |
| M1105 | Metropolitan Medical Center (incl..... The General Hospital) | San Antonio |
| M1136 | North Texas State University..... | Denton |
| M1471 | Rice University..... | Houston |
| M1308 | Texas A & M University System (incl..... Texas Transportation Institute, Texas Agricultural Extension Service, Texas Agricultural Experimental Station, Texas Engineering Extension Service & Texas Engineering Experiment Station) | College Station |
| M1213-XM | Texas Tech University..... | Lubbock |
| M1078 | Texas Tech Univ Health Sciences Center, (incl..... Lubbock General Hosital, RE Thompson General Hospital, TTUHSC @Amarillo, High Plains Baptist Hospital, Harrington Cancer Center, Northwest Texas Hospital, St. Anthony Hospital, VA Hospital @Amarillo, and the Coffee Memorial Blood Center. | Lubbock |
| M1110 | Texas, University of, at Austin..... | Austin |
| M1059-XM | Texas, University of, at Dallas..... | Richardson |
| M1251 | Texas, Univ of, at El Paso..... | El Paso |
| M1098 | Texas, University of, Cancer Ctr (and its.... M.D. Anderson Hosp and Tumor Institute) | Houston |
| M1304 | Texas, Univ of, Health Science Center..... at Dallas | Dallas |
| M1246 | Texas, Univ of, Health Science Center..... at Houston | Houston |

RESTRICTION CODES

XM -- No Medical or IND Studies
 XB -- No Behavioral Studies

MARCH 1985

FIGURE 31 (cont)

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|---------------------|--|-----------------|
| M1403 | Texas, Univ of, Health Science Center..... | San Antonio |
| | at San Antonio, including Med School, Dental School, and Graduate Sch of Biomedical Sciences, Sch of Nursing, Sch of Allied Hlth Sci and Graduate School of Pharmacy, Audie L. Murphy VA Hosital, The Bexar County Hospital District, Southwest Foundation for Biomedical Research, Southwest Research Institute, San Antonio State Chest Hospital, Cancer Therapy Research Center and the Metropolitan Medical Center including the General Hospital. | |
| M1172 | Texas, Univ of, Med Branch at Galveston..... | Galveston |
| <u>UTAH</u> | | |
| M1089 | LDS Hospital - Deseret Foundation..... | Salt Lake City |
| M1152 | Utah State University..... | Logan |
| M1082 | Utah, University of, (includes the..... | Salt Lake City |
| | Research Institute and Veterans Admin Hosp) | |
| <u>VERMONT</u> | | |
| M1375 | Vermont, University of, and State..... | Burlington |
| | Agricultural College | |
| <u>VIRGINIA</u> | | |
| M1355 | Eastern Virginia Medical Authority and..... | Norfolk |
| | Eastern Virginia Medical School | |
| M1195-XM | Human Resources Research Organization..... | Alexandria |
| M1315 | Virginia Commonwealth Univ (All Schools..... | Richmond |
| | and Divisions) | |
| M1343 | Virginia, University of..... | Charlottesville |

RESTRICTION CODES

XM -- No Medical or IND Studies

XB -- No Behavioral Studies

MARCH 1985

INSTITUTIONS WITH A MULTIPLE PROJECT ASSURANCE AS OF MARCH 1985

| ASSURANCE NUMBER | STATE/INSTITUTION | CITY |
|----------------------|---|-------------|
| <u>WASHINGTON</u> | | |
| M1214 | Children's Orthopedic Hosp and Med Ctr..... | Seattle |
| M1008 | Fred Hutchinson Cancer Research Center..... | Seattle |
| M1008 | Swedish Hospital Medical Center..... | Seattle |
| M1040 | Virginia Mason Research Ctr, including..... | Seattle |
| | Mason Clinic and Virginia Mason Hosp | |
| M1076 | Washington Department of Social and Hlth..... | Olympia |
| | Services (All Components) | |
| M1344 | Washington State University..... | Pullman |
| M1183 | Washington, University of..... | Seattle |
| <u>WEST VIRGINIA</u> | | |
| M1044 | Marshall University..... | Huntington |
| M1256 | West Virginia University..... | Morgantown |
| <u>WISCONSIN</u> | | |
| M1392-XM | Marquette University..... | Milwaukee |
| M1061 | Medical College of Wisconsin..... | Milwaukee |
| M1423 | Mendota Mental Health Institute..... | Madison |
| M1120 | Mount Sinai Medical Ctr of Milwaukee..... | Milwaukee |
| M1085 | Southern Wisconsin Center for the..... | Union Grove |
| | Developmentally Disabled | |
| M1285 | Wisconsin, Univ of, Madison Campus..... | Madison |
| M1198 | Wisconsin, University of..... | Milwaukee |
| M1334 | Wisconsin, Univ of, Parkside..... | Kenosha |
| <u>CANADA</u> | | |
| M1458 | McGill University..... | Montreal |

RESTRICTION CODES

XM -- No Medical or IND Studies

XB -- No Behavioral Studies

MARCH 1985

VERTEBRATE ANIMAL 5 POINTS

F. Vertebrate Animals. If you have marked Item 5 on the Face Page of the application "YES," address the following five points.

1. Provide a detailed description of the proposed use of the animals in the work previously outlined in the experimental design and methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and their numbers.
3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices where appropriate to minimize discomfort, distress, pain, and injury.
5. Describe any euthanasia method to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

Although no specific page limitation applies to this section of the application, be succinct.

ANIMAL SUBJECTS

Involvement of live, vertebrate animals for research purposes as described in your proposal (even if at no cost to your proposal and/or if performed at a secondary site) require the submission of the following information to complete your application. Unless received by _____ the review of your application will be deferred to the next review cycle.

- () Applications from institutions that do not have an approved Assurance on file with the Office for the Protection from Research Risks (OPRR), NIH, must contain a declaration that the institution will establish an Institutional Animal Care and Use Committee (IACUC) and submit an Assurance upon request by OPRR. See Note.
- () Applications from institutions with approved Assurances must provide a letter of verification of the date of review by the IACUC signed by the authorized institutional official. See Note.
- () Complete discussion of the following points must be provided:
 - a. identification of the species and approximate number of animals to be used;
 - b. rationale for involving animals, and for the appropriateness of the species and number to be used;
 - c. a complete description of the proposed use of the animals;
 - d. assurance that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and
 - e. a description of any euthanasia method to be used.

Note: The verification or declaration must come from your own institution even if the animal research is to be done at a secondary site.



ADDITIONAL INFORMATION REQUEST LETTER

FIGURE 34

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
Building :
Room :
(301) 496-

(Date)

Re: (application number)

(inside address)

Dear Dr.

In order to facilitate the processing of your application which will be reviewed by the Study Section in , 19 please forward to me, as soon as possible, six (6) copies of the following information:

- ___ Please supply a description of the research supported by
- ___ Also please delineate any scientific or budgetary boundaries or overlaps with the present application.
- ___ Additional information regarding the use, care, and handling of animals. (see attachment)
- ___ A completed HEW-596 form (Human Subjects).
- ___ The 6 points answered for research involving human subjects (see instructions in application kit PHS 398)
- ___ A statement indicating all significant changes made in this amended application.
- ___ Other:

If you have any questions, please call me at 301-496-

Sincerely,

(Exec. Sec.'s name & degree)
Executive Secretary
Study Section
Division of Research Grants

| DEPARTMENT OF HEALTH AND HUMAN SERVICES PROTECTION OF HUMAN SUBJECTS ASSURANCE/CERTIFICATION/DECLARATION | | OMB No. 0930-0047 | |
|---|--|--|--|
| <input type="checkbox"/> ORIGINAL <input type="checkbox"/> FOLLOWUP <input type="checkbox"/> EXEMPTION (previously undesignated) | | <input type="checkbox"/> GRANT <input type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOW <input type="checkbox"/> OTHER <input type="checkbox"/> New <input type="checkbox"/> Competing continuation <input type="checkbox"/> Noncompeting continuation <input type="checkbox"/> Subsequent | |
| | | APPLICATION IDENTIFICATION NO. (if known) | |
| <p>POLICY: A research activity involving human subjects that is not exempt from HHS regulations may not be funded unless a National Review Board (IRB) has reviewed and approved the activity in accordance with Section 474 of the Public Health Service, implemented by Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46—as revised). The applicant institution must certification of IRB approval to HHS unless the applicant institution has designated a specific exemption under Section 46.101(b) applies to the proposed research activity. Institutions with an assurance of compliance on file with HHS which covers the activity should submit certification of IRB review and approval with each application. (In exceptional cases certification accepted up to 60 days after the receipt date for which the application is submitted.) In the case of institutions which do not have assurance of compliance on file with HHS covering the proposed activity, certification of IRB review and approval must be submitted within 30 days of the receipt of a written request from HHS for certification.</p> | | | |
| 1. TITLE OF APPLICATION OR ACTIVITY | | | |
| 2. PRINCIPAL INVESTIGATOR, PROGRAM DIRECTOR, OR FELLOW | | | |
| 3. FOOD AND DRUG ADMINISTRATION REQUIRED INFORMATION (see reverse side) | | | |
| 4. HHS ASSURANCE STATUS | | | |
| <input type="checkbox"/> This institution has an approved assurance of compliance on file with HHS which covers the activity. _____ Assurance identification number _____ IRB identification number | | | |
| <input type="checkbox"/> No assurance of compliance which applies to this activity has been established with HHS, but the applicant institution will provide written assurance of compliance and certification of IRB review and approval in accordance with 45 CFR 46 upon request. | | | |
| 5. CERTIFICATION OF IRB REVIEW OR DECLARATION OF EXEMPTION | | | |
| <input type="checkbox"/> This activity has been reviewed and approved by an IRB in accordance with the requirements of 45 CFR 46, including its relevant Subparts. The institution fulfills, when applicable, requirements for certifying FDA status for each investigational new drug or device. (See reverse side of this form for details.) _____ Date of IRB review and approval. (If approval is pending, write "pending." Followup certification is required.) (month/day/year) | | | |
| <input type="checkbox"/> Full Board Review <input type="checkbox"/> Expedited Review | | | |
| <input type="checkbox"/> This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects are reviewed and approved before they are initiated and that appropriate further certification (Form HHS 596) will be submitted. | | | |
| <input type="checkbox"/> Human subjects are involved, but this activity qualifies for exemption under 46.101(b) in accordance with paragraph _____ (insert paragraph of exemption in 46.101(b), 1 through 5), but the institution did not designate that exemption on the application. | | | |
| 6. Each official signing below certifies that the information provided on this form is correct and that each official assumes responsibility for assuring required future reviews, approvals, and submissions of certification. | | | |
| APPLICANT INSTITUTION | | COOPERATING INSTITUTION | |
| NAME, ADDRESS, AND TELEPHONE NO. | | NAME, ADDRESS, AND TELEPHONE NO. | |
| NAME AND TITLE OF OFFICIAL (print or type) | | NAME AND TITLE OF OFFICIAL (print or type) | |
| SIGNATURE OF OFFICIAL LISTED ABOVE (and date) | | SIGNATURE OF OFFICIAL LISTED ABOVE (and date) | |

(If additional space is needed, please use reverse side of form.)

FIGURE 35 (cont)

FOOD AND DRUG ADMINISTRATION REQUIRED INFORMATION (from front side)
According to 45 CFR 46.121, if an application is made to HHS requiring certification and involving use of an investigational new drug or device additional information is required. In addition, according to 21 CFR 312.1(a)(2), 30 days must elapse between date of receipt by FDA of Form FD 1571 and use of the drug, unless the 30 day delay period is waived by FDA.

INVESTIGATIONAL NEW DRUG EXEMPTION (if more than one is involved, list others below under NOTES)

SPONSOR NAME

DRUG NAME

DATE OF END OF 30-DAY EXPIRATION OR WAIVER

NUMBER ISSUED

INVESTIGATIONAL DEVICE EXEMPTION:

SPONSOR NAME

DEVICE NAME

Unless notified otherwise by FDA, under 21 CFR 812.2(b) (ii) a sponsor is deemed to have an approved IDE if: (1) the IRB has agreed with the sponsor that the device is a nonsignificant risk device; and (2) the IRB has approved the study. (Check applicable box.)

☐ The IRB agrees with the sponsor that this device is a nonsignificant risk device.

☐ The IDE application was submitted to FDA on (date) _____, Number issued _____.

NOTES.

DISTRIBUTION CHART

Rev 9/87

| Institute/ Program | Meeting List | Summary Statements | Deferred Applications | Send to: Name/Location | Telephone Number |
|-----------------------|-----------------|------------------------|--------------------------|---|---------------------|
| AG | 4 | 25 | 20 | Grants Mgmt., 31/5C39 | 496-1472 |
| AI/ R, K | 3 | 30 | 15 | Margaret Cattafesta, WB/725 | 496-7201 |
| F32, F33 | | 30 | | | |
| AR/ R, K | 1 | 50 | 5 | Mail & Files, EP, WB/618 | 496-7387 |
| F32, F33 | | 10 | | Send Apps. & Summaries to WB/606 | |
| T35 | | 30 | | | |
| CA/ R, K, P | 5 | 20 | 15 | Board Preparation, WB/848 | 496-7987 |
| & T32 | | | | | |
| F32, F33 | 3 | 20 | -- | Elaine Sirkis, Blair Bldg., Rm. 428 | 427-8866 |
| DE/F32, F33 | 2* | 20 | 10 | Sheryl Rathke, WB/518 | |
| R,K,P,T-32 | | 85 | 10 | | |
| | | (*15 from OBM SS only) | | Send Apps. only to Linda Edwards, WB/518 | |
| DK/ R, K | 1 | 30 | | Mail & Files, EP, WB/606 | |
| F32, F33 | | | | | |
| ES/ | 1 | 1 | -- | Extramural Programs, Grants Processing, FTS-8 P.O. Box 12233, Res. Triangle Park, NC 27709 | |
| | | (orig.) | | | |
| EY/ R & K | 2 | 80 | 10 | Lilyan Atkinson, 31/6A46 | 496-5884 |
| F32, F33 | 2 | 15 | 10 | Robin Richardson, Bg.31/6A46 | 496-5884 |
| T32, T35 | 2 | 80 | 10 | | |
| GM/ R & K | 2 | 75 | 10 | Fuller Ming, WB/940 | 496-7435 |
| F32, F33 | 2 | 25 | 10 | | |
| HD/ R, K, | 3 | 80 | 25 | Myrtle Coleman | 496-6351 |
| T32 | 3 | | | Landow Bldg., Rm. 6A12 | |
| F32, F33 | 3 | 35 | 25 | | |
| HL/ R | 2 | 6 | 15 | Vacant, WB/4A09 | 496-7536 |
| K, F32, F33 | 4 | 6 | 15 | | |
| & T32 | | | 10 (duals) | | |
| LM/ R | 3 | 60 | 50 | Dawn Carlisle, 38A/5N510 | 496-4253 |
| NS/ R | 1 | 100 | 10 | Gordon Whitt | 496-9251 |
| K, T32 | 1 | 100 | 10 | Federal Bldg, Rm. 10C14 | |
| F32, F33 | 1 | 30 | 10 | | |
| RR/ M01 | 2 | * | 1 | Dr. Michael Oxman, Chief Office of Review | 496-4390 |
| n/a 224 | | | | Director of Res. Resour. | |

FIGURE 36 (cont)

| | | | | | |
|---|----|----|----|---|--|
| <u>DA</u> | 3 | 85 | 2 | Carolyn Carlo, Parklawn/10-42 | 9-443-2620 |
| <u>FD</u> | -- | 45 | -- | Katheryn McKnight, Parklawn/15A17 | 9-443-6170 |
| <u>HS</u> and <u>HT</u> | 1 | 5 | -- | John Gallicchio, Park Bldg./1-52 | 9-443-3091 |
| | 1 | 5 | -- | (Correspondence-Ralph Sloat, Park Bldg./1-43) | 9-443-4033 |
| <u>MH</u> | 2 | 75 | -- | Rachel Driver, Parklawn/9-105 | 9-443-3367 |
| <u>NR</u> | 3 | 50 | -- | Ruth Aladj, Bg., 38A/B2E17A | 496-0526 |
| <u>OH</u> Laser copies and resumes ONLY (NO COMPUTER HOOK-UP, MUST BE MAILED ASAP) | 2 | 30 | -- | Dr. Roy Flemming NIOSH Bldg. 1, Room 3053 Atlanta, GA 30333 | FTS 8-236-3343 non-FTS 404 329 3343 |
| Summary Statements | | | | Mr. Leo Sanders NIOSH 255 E. Paces Ferry Road Rm. 321 Atlanta, GA 30333 | FTS 8-236-6575 non-FTS 404 262 6575 |

DISTRIBUTION CHART (Continued)

| Special Distribution | Meeting List | Summary Statements | Resume of Recommendations | Send to: Name/Location | Telephone Number |
|---|---|--------------------|---------------------------|--|--|
| All Programs | 1 | 1 xerox copy | 1 | BHNS: Jenny Bogley, 340, WB BIOL: Linda Robbins, 340, WB BIOM: Virginia Shifflett, 348, WB CLIN: Betty Lester, 340, WB PHYS: Diane Martin, 348, WB SSS: Genevieve Pearsall, 2A16 WB | 496-7248 496-8844 496-7071 496-7248 496-7072 496-7558 |
| All Programs | 1 | -- | 1 | Thelma Sams, Rm. 118, WB | 496-7155 |
| All Programs | Send 1 application and 1 summary statement for human and animal subjects coded 32, 44, 47, and 49 | 1 | 1 | Helen Gordon, Bg. 31, Rm. 4B09 | 496-7041 |
| Fellowships (F32's, F-33's and resumes) | Send 1 complete set of summary statements | | | Nick Moriarty, Rm. A27, WB | 496-7221 |
| Special Study Section (SSS) | Distribute: 5 rosters (prior to review) 1 summary statement - laser copy | | | Genevieve Pearsall, Rm. 2A16, WB | 496-7558 |

NOTE: When preparing Printing Requisitions, request Institute's required number and delivery point plus 10 additional copies for direct delivery to persons preparing requisition.

SPECIAL INSTRUCTIONS ON DISTRIBUTION:

Additional Information: Send original to the appropriate Institute.

Appendix Material: Send one complete set to the first assigned Institute.

Project Site Visit Report: Send a copy to the appropriate Institute.

DISTRIBUTION CHART (Continued)

Agenda of Study Section/Review Group Meetings: 2 to appropriate Lead Grants Technical Assistant

Be sure agenda is put in computer at least 2 weeks before meeting.

Rosters of Study Section Members:

- (1) Be sure roster is in laser well before Study Section meeting.
- (2) Send to Assistant Chief of your Section.
- (3) Send five (5) copies to Conference Services Center, Room 6C-17, Building 31, before Study Section meeting (even if held off reservation).
- (4) Attach Study Section rosters (including Special Reviewers and Executive Secretary and Grants Assistant) to all copies of summary minutes.
- (5) Include rosters as the last page of summary statements, identified at the top of the page with the application number and page number.

SUMMARY MINUTES

Summary Minutes and Roster (not including resume of recommendation or summary statements) should be distributed as follows:

- 1 to appropriate Lead Grants Technical Assistant (for proofing prior to signatures of Executive Secretary and Chairperson and distribution)
- 1 to each Study Section member
- 1 to each Institute for which the Study Section reviewed applications
- 1 to Information Office, Room 449, Westwood Building
- 1 (original) to Committee Management Office, Room 453, Westwood Building

SUMMARY STATEMENTS

1. Send a laser copy to appropriate Lead Grants Technical Assistant for review as soon as typed.
2. Send a copy to appropriate Institute(s) at the time printed copies are received from laser printer.
3. Refer requests for summary statements from outside DRG to the appropriate Institute.
4. Send a copy of each summary statement involving a multi-project application to Research Documentation Section, Room 148B, Westwood Building.

PROJECT CONTROL USE ONLY

DATE:

REQUEST FOR ASSIGNMENT CHANGE(S)

TO Referral Office, Westwood Bldg., Room 248

REQUESTED BY: _____ Tele.# _____

THROUGH: GRANTS TECHNICAL ASSISTANT: _____ Tele.# _____

PRINCIPAL INVESTIGATOR _____

CURRENT ASSIGNMENT

| | Code | B/I/D(s) | Number | Year | IRG | Council |
|--|------|----------|-------------|------|-----------|---------|
| <u>PROPOSED CHANGE(S):</u> | | | <u>FROM</u> | | <u>TO</u> | |
| <input type="checkbox"/> IRG | | | _____ | | _____ | |
| <input type="checkbox"/> COUNCIL DATE | | | _____ | | _____ | |
| <input type="checkbox"/> ADMINISTRATIVELY DEFERRED: | | | | | | |
| <input type="checkbox"/> IRG | | | _____ | | _____ | |
| <input type="checkbox"/> COUNCIL DATE | | | _____ | | _____ | |
| <input type="checkbox"/> CHANGE IN APPLN. NUMBER | | | _____ | | _____ | |
| <input type="checkbox"/> MULTIPLE B/I/D COUNCIL REVIEW | | | _____ | | _____ | |
| <input type="checkbox"/> WITHDRAWN | | | _____ | | _____ | |
| <input type="checkbox"/> RETURNED TO APPLICANT | | | _____ | | _____ | |

BACKGROUND/JUSTIFICATION LEADING TO REQUESTSTAFF CONSULTED:

APPROVED BY:

FIGURE 38

DAILY TRANSACTION LIST

DATE 01/27

PREPARED BY SYSTEM & DATA MANAGEMENT SECTION, SAB, DRG

| APPLICATION/GRANT NO DUAL PCC | NAME ACTIONS | IRG | COUNCI DAT |
|----------------------------------|--|-------|---------------|
| 1 R01 AG04820-01 AM 1HZ1 | OBERLEY, TERRY D INITIAL REVIEW GROUP CHANGED TO | CBY 2 | CP 05-84 |
| 1 K04 AM01264-01 7D | DRICKAMER, KURT INITIAL REVIEW GROUP CHANGED TO | CBY 2 | CP 05-84 |
| 2 R01 CA23016-08 23L42818 | KELLER, JOHN M INITIAL REVIEW GROUP CHANGED TO | CBY 2 | CP 05-84 |
| 1 R13 GM33598-01 NS | LEFKOWITZ, ROBERT J INITIAL REVIEW GROUP CHANGED TO | CBY 2 | CP 05-84 |

PROJECT CONTROL USE ONLY

DATE:

REQUEST FOR ASSIGNMENT CHANGE(S)

TO Referral Office, Westwood Bldg., Room 248

REQUESTED BY: _____ Tele.# _____

THROUGH: GRANTS TECHNICAL ASSISTANT: _____ Tele.# _____

PRINCIPAL INVESTIGATOR _____

CURRENT ASSIGNMENT

| | Code | B/I/D(s) | Number | Year | IRG | Council |
|--|------|----------|-------------|------|-----------|---------|
| <u>PROPOSED CHANGE(S):</u> | | | <u>FROM</u> | | <u>TO</u> | |
| <input type="checkbox"/> IRG | | | _____ | | _____ | |
| <input type="checkbox"/> COUNCIL DATE | | | _____ | | _____ | |
| <input type="checkbox"/> ADMINISTRATIVELY DEFERRED: | | | | | | |
| <input type="checkbox"/> IRG | | | _____ | | _____ | |
| <input type="checkbox"/> COUNCIL DATE | | | _____ | | _____ | |
| <input type="checkbox"/> CHANGE IN APPLN. NUMBER | | | _____ | | _____ | |
| <input type="checkbox"/> MULTIPLE B/I/D COUNCIL REVIEW | | | _____ | | _____ | |
| <input type="checkbox"/> WITHDRAWN | | | _____ | | _____ | |
| <input type="checkbox"/> RETURNED TO APPLICANT | | | _____ | | _____ | |

BACKGROUND/JUSTIFICATION LEADING TO REQUESTSTAFF CONSULTED:APPROVED BY:

Chapter VI

REVIEW OF APPLICATIONS BY THE EXECUTIVE SECRETARY

A. ASSIGNEES AND ASSIGNMENT LIST

1. Assignees

Each study section member receives all applications for review by the study section at the next meeting, except for applications submitted by the member's own organization or applications for which any other potential conflict of interest exists. Those applications are omitted from that member's workbook. For reference, see Chapter XV, Section A. Study section members are expected to read or be familiar with all the applications so as to be able to participate in their discussion at the next study section meeting.

For each application, the Executive Secretary also selects certain members, called "assignees," to provide an in-depth review. Usually at least two assignees are chosen by the Executive Secretary for each application. Assignees are expected to prepare detailed written reviews for which they are provided Guidelines (Figure 40). These guidelines are kept in the third floor duplicating room (Room 336). Multicolor snapout forms, also located in the third floor duplicating room, are often used on which assignees may type their comments (Figure 41). Some Executive Secretaries ask that these reviews be submitted prior to the study section meeting with one copy kept by the assignee.

Assignees must be selected and advised about their in-depth review assignments as soon as possible after receipt of the applications. Review assignments should be mailed to members 6 to 8 weeks before the study section meetings. If assignees feel that additional information is needed or that outside opinions would be useful, they should ask the Executive Secretary to obtain this information. Assignees must not request outside opinions on their own, and must not communicate with the principal investigator directly.

2. Assignment List

A partial assignment list is sometimes prepared in order to mail applications as soon as possible. When all applications have been received and assigned, a final assignment list is prepared and sent to the entire membership (Figure 42). Assignment lists (minus the assignees' names) can be obtained directly from the computer. (Instructions are available in the User Resource Office).

Copies of assignment lists or other documents indicating the names of the assignees on specific applications must not be distributed to persons other than study section members and DRG office staff.

B. ADDITIONAL INFORMATION

When applications are deficient in such areas as the description of the methodology or research design, the justification for budget items, or the explanation for requests for equipment, the Executive Secretary contacts the principal investigator for the needed information. These requests should be made as soon as possible, since the principal investigator's reply must be duplicated and sent to study section assignees prior to the meeting.

The Executive Secretary's written request for additional information may be an original or form letter (Figures 43 and 43a). The Grants Assistant files one copy of each letter in the study section file, and distributes additional copies to the appropriate Institute.

The principal investigator's reply, identified with the grant application number, is duplicated for the study section file, for the Executive Secretary's workbook, and for the assignees. The original incoming letter is forwarded to the Institute. To save the time and expense of duplicating every reply, the original request should instruct the principal investigator to provide a specified number of copies of the information.

Additional information in the form of reprints, lengthy manuscripts, and other bulky materials should be sent to assignees, but should not be duplicated. Instead, the required number of copies should be requested from the principal investigator. Occasionally, the Grants Assistant will have to note on these copies "Please Return for Study Section File," and then check the list of materials still to be retrieved at the meeting.

Copying should be kept to a minimum. It is unnecessary for every study section member to receive a copy of all the preceding materials.

C. OUTSIDE OPINIONS

When the Executive Secretary or a study section member feels that some phase of the proposed project requires additional scientific advice, the Executive Secretary requests an outside opinion. A book entitled Competency Rosters of NIH Initial Review Groups, which is available in the Committee Management Office, may be useful to the Executive Secretary in identifying experts in specific areas.

Before requesting an opinion from a member of another study section, another Institute review group, or a Council, the Executive Secretary should contact the appropriate Executive Secretary or supervisor. An opinion should never be requested from a member of a Council to which an application is assigned.

When outside opinions are requested, reviewers should be informed that their opinions will be confidential and disclosed only to the study section, unless otherwise requested by the applicant under the Privacy Act.

For an outside opinion, the Grants Assistant should send the application, appendix material (optional), appropriate Guidelines (Figure 40), NIH Conflict of Interest Policy and Certification (Figure 44 which should be signed by the reviewer and returned), and a business reply label or

envelope. The signed NIH Conflict of Interest Policy and Certification should be kept in the minutes file of the study section. A copy of the request letter is sent to the Institute to which the application has been assigned. A copy of the outgoing letter may also be kept in the study section file, or a log may be attached to the file copy of the minutes. The log should contain the application number, the principal investigator, the name of the person from whom the opinion is requested, and whether the opinion was received. A copy of the outside opinion is not placed in the file and not sent to the Institute.

All copies should be discarded immediately after the summary statement has been prepared by the Executive Secretary. See Figure 45 for a sample form letter requesting an outside opinion and thanking the reviewers for their advice.

J. PROJECT SITE VISITS

Occasionally, project site visits are made prior to the study section meeting. (See Chapter XII.)

K. RESPONSIBILITIES OF THE GRANTS ASSISTANT

The Grants Assistant is involved in each of the tasks associated with the review of the application by the Executive Secretary. For example, the Grants Assistant prepares the study section assignment list and a transmittal memo for each mailing, and has them duplicated. The Grants Assistant also prepares letters to the principal investigator, requests for outside opinions, and any correspondence to study section members in the interim between meetings.

GUIDE FOR ASSIGNED REVIEWERS' PRELIMINARY COMMENTS ON RESEARCH GRANT APPLICATIONS (R01)

With the advent of the latest (9/86) revision of Form PHS 398, reviewers need to be aware of several issues that will affect the manner in which applications are evaluated. Additionally, during the period of transition to the new form, it is likely that the older form will be used by some applicants. It is important that all applications be reviewed taking into account the features or limitations of the specific form used.

The most significant change in the new form is the imposition of a 20-page limit on Sections A through D: Specific Aims, Background and Significance, Progress Report/Preliminary Studies, and Experimental Design and Methods. The Principal Investigator is requested to provide only an outline in the Experimental Design and Methods section. An appendix is still allowed, but it may not include more than 10 published or accepted manuscripts. Reviewers must take into account that these limitations preclude the level of detail requested previously, and applicants should not be penalized for failure to provide the detail to which the study sections have become accustomed. On the other hand, investigators who use the older form should be neither advantaged nor disadvantaged by having provided a longer, more detailed application.

Total costs are requested on the new application form along with direct costs. Indirect costs must not influence the priority score or the assessment of the budget.

Please use the following guidelines when preparing written comments on research grant applications assigned to you for review.

DESCRIPTION: Use the abstract on page 2 of the application unless inappropriate, making sure the objectives and procedures are clearly and concisely described. Do not make evaluative statements as part of the description.

CRITIQUE: Do not include descriptive information in this section. Provide an analysis of the strengths and weaknesses of the research plan, which consists of Specific Aims, Background and Significance, Progress Report/Preliminary Studies, and Experimental Design and Methods. For deferred or revised applications, evaluate changes since the previous review.

NOTE: The new application form requests only an outline of Experimental Design and Methods, and page limitations preclude the level of detail requested in the past.

INVESTIGATORS: Assess the competence of the principal investigator and key personnel to conduct the proposed research.

RESOURCES AND ENVIRONMENT: Evaluate any special attributes or deficiencies relevant to the conduct of the proposed studies.

BUDGET: Evaluate the direct costs only. Determine whether all items of the budget are appropriate and justified. Provide a rationale for each suggested modification in amount or duration of support. For supplemental applications, comment on the requested budget in relation to the parent grant.

OTHER CONSIDERATIONS

Overlap: Identify any apparent scientific or budgetary overlap with active, pending, or planned support.

Foreign: Comment on any special talents, resources, populations, or environmental conditions that are not readily available in the United States or that provide augmentation of existing United States resources. In addition, indicate whether similar research is being done in the United States and whether there is a need for such additional research. In the case of a domestic application with a significant foreign component, apply the same criteria.

Human Subjects

Exemptions Claimed: Express any comments or concerns about the appropriateness of the exemption(s) claimed.

No Exemptions Claimed: Express any comments or concerns about the appropriateness of the responses to the six required points, especially whether the risks to subjects are reasonable in relation to the anticipated benefits to the subjects and in relation to the importance of the knowledge that may reasonably be expected to result from the research.

Vertebrate Animals: Express any comments or concerns about the appropriateness of the responses to the five required points, especially whether the procedures will be limited to those that are unavoidable in the conduct of scientifically sound research.

Biohazards: Note any materials or procedures that are potentially hazardous and indicate whether the protection proposed will be adequate.

SUMMARY AND RECOMMENDATION: Summarize the strengths and weaknesses of the application and provide a recommendation of approval, disapproval, or deferral. You may recommend a priority rating.

NOTE: Your written comments will be destroyed after being incorporated into the summary statement. However, they should not bear personal identifiers because, under the Privacy Act of 1974, principal investigators may, upon request, gain access to documents relating to the review of their grant applications. In the rare event that your comments must be made available to a Principal Investigator, you will be notified promptly by NIH staff.

August 1987

FIGURE 40 (cont.)

GUIDE FOR ASSIGNED REVIEWERS' PRELIMINARY COMMENTS ON
RESEARCH CAREER DEVELOPMENT AWARD APPLICATIONS (K04)

The Research Career Development Award (RCDA) is designed to enhance the research capability of individuals in the formative stages of their careers who have demonstrated outstanding potential for contributing as independent investigators to health-related research. The awards are available for persons whose research potential is apparent but who need additional experience in a productive scientific environment conducive to the development of a career in independent research.

Candidates should normally have five years of relevant postdoctoral experience including two years of experience as an independent investigator with independent peer-reviewed grant support. Applicants who did not meet this criteria can qualify if they demonstrate in the application that they have achieved an equivalent level of experience and independence. The application must document accomplishment in this period that demonstrates research potential; it must also present a plan for additional experience in a productive scientific environment that will foster development of a career in independent research.

The RCDA is not intended for untried investigators, or for productive, independent investigators with significant numbers of publications of high quality, or for persons of senior academic rank. Moreover, the award is not intended to substitute one source of salary support for another for an individual who is already conducting full-time research, nor is it intended to be a mechanism for providing institutional support. The application must demonstrate that the award will make a difference in and enhance the candidate's development as an independent investigator.

* * * * *

CANDIDATE. Evaluate the adequacy of the candidate's background as a guide to future development into a creative, independent investigator. Factors to be considered include the quality and extent of past education, scientific training and research experience; need for further research experience and/or training; evidence of superior performance, originality, independence, and productivity; quality of any independent research publications; commitment to health-related research; and letters of reference.

RESEARCH PLAN. Assess the merit of the candidate's research proposal, including the significance and originality of the proposed study in its scientific field, the reasonableness and significance of the hypothesis, the logic of the aims, the feasibility and adequacy of the procedures for the proposed research, and the adequacy of the plans for analysis and evaluation of data. Analyze whether the research is likely to produce new data and concepts.

ENVIRONMENT. Evaluate the adequacy of the environment in terms of the availability of space and equipment resources, facilities, technical assistance, and opportunities for critical professional interaction with senior colleagues as pertinent to the proposed research plan and any other research career development plans. Identify and assess the adequacy of the research support funds that will be available to the candidate during the period of the Award.

(over)

Evaluate the institution's commitment to and plans for the candidate during the five year period. The institution must guarantee that if an award is made, the applicant will have at least 80% of his/her time available for research. Determine whether the institution is willing to permit the candidate to spend essentially full time in the actual conduct of research and research-related activities, such as supervision of research trainees and attendance at meetings. For those candidates who are already engaged full time in research, assess how the award would enhance their career development.

BUDGET. Do not recommend changes in the budget and years requested. The award is for a single support period of five years at a salary (up to a maximum of \$30,000 per year) consistent with the policy of the sponsoring institution.

OTHER CONSIDERATIONS:

Involvement of Human Subjects.

Exemptions Claimed. Evaluate the appropriateness of the claimed exemptions.
or

No Exemptions Claimed. Assess the appropriateness of the subject population. Explain any potential physical, psychological, social, or legal risks to individuals who are participating as subjects in research, development, or related activities. Describe the procedures for protecting against or minimizing such risks, and discuss whether the risks are reasonable in relation to the anticipated benefits to subjects and the importance of the knowledge that may reasonably be expected to result. Assess the adequacy of the consent procedures.

Animal Welfare. If vertebrate animals are to be used in the project, discuss the appropriateness of the choice of species and numbers involved, and the justification for their use. Assess whether the animals will receive proper care and maintenance, and will not suffer unnecessary discomfort, pain, or injury. Special attention should be provided when the proposed research involves dogs, cats, nonhuman primates, or large numbers of animals.

Hazardous Materials and Procedures. Describe any potentially hazardous materials and procedures and whether the protection to be provided will be adequate.

SUMMARY AND RECOMMENDATION. Provide an overall evaluation of the strengths and weaknesses of the application. Assess what difference the tenure of an Award will make to the candidate's research career development and provide a recommendation of approval, disapproval, or deferral.

* * * * *

NOTE. Under the Privacy Act of 1974, principal investigators may have access, upon request, to documents generated during the review of their grant applications. You do not have to sign written comments, and your comments will be destroyed after being incorporated into the summary statement. In the event that your comments must be made available to the principal investigator, you will be promptly notified by NIH staff.

Revised August 1987

GUIDE FOR ASSIGNED REVIEWERS' PRELIMINARY COMMENTS ON (R29)
FIRST INDEPENDENT RESEARCH SUPPORT AND TRANSITION AWARD APPLICATIONS

The First Independent Research Support and Transition (FIRST) program (R29) is designed to provide a sufficient initial period of research support for newly independent biomedical investigators to develop their research capabilities and demonstrate the merit of their research ideas. These grants are intended to underwrite the first independent investigative efforts of an individual; to provide a reasonable opportunity for him/her to demonstrate creativity, productivity, and further promise; and to help effect a transition toward the traditional types of NIH research project grants.

The principal investigator must be a beginning investigator who is not in training status at the time the award will begin. This award is not intended for mid career transition to other research endeavors. A FIRST award is for a distinct research endeavor and may not be used merely to supplement or broaden an ongoing project at the applicant institution.

FIRST awards are made for a period of five years. These awards are not renewable. The total direct costs awarded must not exceed \$350,000 for the 5 years, with no more than \$100,000 for any one year. Principal investigators must make a truly significant commitment of time or effort, at least 50%, to the proposed research project in each budget period.

Please use the following guidelines when preparing written comments on research grant applications assigned to you for review.

DESCRIPTION: Use the abstract on page 2 of the application unless inappropriate. Do not make evaluative statements in this section.

CRITIQUE: Do not include descriptive information in this section. Provide an analysis of the strengths and weaknesses of the research plan, which consists of Specific Aims, Background and Significance, Preliminary Studies, and Experimental Design and Methods. For deferred or revised applications, evaluate changes since the previous review.

NOTE: A principal investigator for a FIRST Award is less likely to be able to submit an application in the same breadth and depth as an experienced investigator. For example, protocols for the fourth and fifth years may not be as specific as seen in most RO1 applications.

INVESTIGATORS. Assess the competence of the principal investigator and key personnel to conduct the proposed research. Also assess whether the principal investigator is an independent, beginning investigator with a five year commitment to the proposed research. Evaluate the required letters of reference.

RESOURCES AND ENVIRONMENT. Evaluate any special attributes or deficiencies relevant to the conduct of the proposed studies. Also evaluate the commitment of the applicant organization to the project for the five year period.

BUDGET. Evaluate the direct costs only. Determine whether all items of the budget are appropriate and justified. Provide a rationale for any suggested modification. Only in very unusual circumstances may the recommended duration of support be less than five years.

OTHER CONSIDERATIONS

Overlap. Identify any apparent scientific or budgetary overlap with active or pending support.

Human Subjects.

Exemptions Claimed. Express any comments or concerns about the appropriateness of the exemption(s) claimed.

No Exemptions Claimed. Express any comments or concerns about the appropriateness of the responses to the six required points, especially whether the risks to subjects are reasonable in relation to the anticipated benefits to the subjects and in relation to the importance of the knowledge that may reasonably be expected to result from the research.

Vertebrate Animals: Express any comments or concerns about the appropriateness of the responses to the five required points, especially whether the procedures will be limited to those that are unavoidable in the conduct of scientifically sound research.

Biohazards: Note any materials or procedures that are potentially hazardous and indicate whether the protection proposed will be adequate.

SUMMARY AND RECOMMENDATION. Summarize the strengths and weaknesses of the application and provide a recommendation of approval, disapproval, or deferral. You may recommend a priority rating.

NOTE: Your written comments will be destroyed after being incorporated into the summary statement. However, they should not bear personal identifiers because, under the Privacy Act of 1974, principal investigators may, upon request, gain access to documents relating to the review of their grant applications. In the rare event that your comments must be made available to a Principal Investigator, you will be notified promptly by NIH staff.

August 1987

ACADEMIC RESEARCH ENHANCEMENT AWARD (R15)
GUIDE FOR ASSIGNED REVIEWERS' PRELIMINARY COMMENTS

The National Institutes of Health (NIH) is making a special effort to stimulate research in educational institutions which provide the baccalaureate training for a significant number of our nation's research scientists but which historically have not been major participants in NIH programs. Funds have been added to the NIH budget specifically for the AREA program and for the objectives stated.

AREA grants are for the support of new or expanded health-related research projects conducted by faculty in institutions that are not research intensive. The AREA will enable qualified individual scientists to receive support for feasibility studies and other small scale research projects. These grants create a research opportunity for scientists and institutions, otherwise unlikely to participate extensively in NIH programs, to contribute to the nation's biomedical research effort. It is anticipated that principal investigators supported under the AREA Program will benefit from this unique opportunity to conduct independent, preliminary research studies preparatory to seeking more substantial funding through other traditional NIH grant mechanisms; that the awardee institution will benefit from the strengthened research environment, initiated through AREA grants and furthered by participation in the diverse extramural programs of the NIH; and that students will benefit from exposure to, and participation in, research and thus be encouraged to pursue graduate studies in the health sciences.

Institutions eligible for the Biomedical Research Support Grant (BRSG) for more than three of the past seven years are ineligible to apply for an Academic Research Enhancement Award (AREA). Special consideration will be given in the funding decision process to applications recommended for approval from those smaller, less prominent, four-year, public and private colleges and universities which provide undergraduate training for a significant number of our nation's research scientists but which have not shared adequately in the growth of the NIH extramural program.

The amount of support requested in each application may be up to \$50,000 in direct costs which may be expended over a period of up to 24 months.

Please use the following guidelines when preparing written comments on AREA applications assigned to you for review.

DESCRIPTION: Use the abstract on page 2 of the application unless inappropriate, making sure the objectives and procedures are clearly and concisely described. Do not make evaluative statements as part of the description.

CRITIQUE: Do not include descriptive information in this section. Provide an analysis of the strengths and weaknesses of the research plan, which consists of Specific Aims, Background and Significance, Progress Report/Preliminary Studies, and Experimental Design and Methods. Evaluate the project's potential as a basis for more extensive research.

NOTE: Stringent page limitations apply. Furthermore since AREA applications are requests for support of small scale research projects, including pilot or feasibility studies, preliminary data may not be provided.

INVESTIGATORS: Assess the competence of the principal investigator and key personnel to conduct the proposed research.

RESOURCES AND ENVIRONMENT: Evaluate any special attributes or deficiencies relevant to the conduct of the proposed studies.

BUDGET: Evaluate the direct costs only. Determine whether all items of the budget are appropriate and justified. Provide a rationale for each suggested modification in amount or duration of support.

OTHER CONSIDERATIONS

Overlap: Identify any apparent scientific or budgetary overlap with active, pending, or planned support.

Human Subjects

Exemptions Claimed: Express any comments or concerns about the appropriateness of the exemption(s) claimed.

No Exemptions Claimed: Express any comments or concerns about the appropriateness of the responses to the six required points, especially whether the risks to subjects are reasonable in relation to the anticipated benefits to the subjects and in relation to the importance of the knowledge that may reasonably be expected to result from the research.

Vertebrate Animals: Express any comments or concerns about the appropriateness of the responses to the five required points, especially whether the procedures will be limited to those that are unavoidable in the conduct of scientifically sound research.

Biohazards: Note any materials or procedures that are potentially hazardous and indicate whether the protection proposed will be adequate.

SUMMARY AND RECOMMENDATION: Summarize the strengths and weaknesses of the application and provide a recommendation of approval, disapproval, or deferral. You may recommend a priority rating.

NOTE: Your written comments will be destroyed after being incorporated into the summary statement. However, they should not bear personal identifiers because, under the Privacy Act of 1974, Principal Investigators may, upon request, gain access to documents relating to the review of their grant applications. In the rare event that your comments must be made available to a Principal Investigator, you will be notified promptly by NIH staff.

August 1987

GUIDE FOR REVIEWER'S PRELIMINARY COMMENTS ON SHORT-TERM TRAINING GRANT, APPLICATIONS (T35)

Please use the following general guidelines when preparing written comments on short-term training grant applications assigned to you for review.

DESCRIPTION. Briefly describe the major features of the proposed research training program. Include the number of individuals to be trained, the duration of training, the discipline(s) and/or specialty area(s) of training, the method of recruitment and selection of trainees, the administrative structure of the program, and the institution's plans for assessing the impact of the program on the institution and trainees. Do not make evaluative statements in this section.

CRITIQUE. Evaluate the program design, including the recruitment and selection procedures, and its potential for attracting students to careers in clinical investigation. Evaluate the institution's plans for assigning trainees, for monitoring their progress, and for assessing the impact of the program on the institution and trainees.

FACULTY. Evaluate the competence of the program director and key staff to conduct the proposed program, including their academic qualifications, research and training experience and productivity, time commitment to the program, and research support.

RESOURCES AND ENVIRONMENT. Evaluate the quality of the environment, including the trainees' opportunities for contact with a variety of scientists and the availability of necessary resources (Laboratory, animal, research support, etc.). Evaluate the institution's commitment to the training of clinical investigators by assessing its current training program and past training record.

BUDGET. Determine the number of students the program can productively accommodate each year. Any adjustments from the requested number should be explained. Identify any budgetary items that are unnecessary; if none, the NIH will negotiate the balance of the budget up to \$250 per student per month following program guidelines.

OTHER CONSIDERATIONS

Because of the nature of training grant applications, the applicant is not asked to provide specific information on risks to human subjects, animal welfare or hazardous materials. However, any problems anticipated in these areas should be noted for subsequent followup.

SUMMARY AND RECOMMENDATION. Summarize the strengths and weaknesses of the application. Provide the key reasons for your recommendation of approval or disapproval and any budget changes.

* * * * *

NOTE. Under the Privacy Act of 1974, program directors may have access, upon request, to documents generated during the review of their grant applications. You do not have to sign written comments, and your comments will be destroyed after being incorporated into the summary statement. In the event that your comments must be made available to a program director, you will be promptly notified by NIH staff.

DRG/NIH
March 12, 1980

GUIDE FOR REVIEWERS PRELIMINARY COMMENTS ON
NATIONAL RESEARCH SERVICE AWARD SENIOR FELLOWSHIP APPLICATIONS (F33)

The senior fellowship is designed to provide opportunities for experienced scientists to make major changes in the direction of their research careers, to broaden their scientific background, to acquire new research capabilities, or to enlarge their command of an allied research field. In addition, these awards will enable individuals beyond the new investigator stage to take time from regular professional responsibilities for the purpose of increasing their capabilities to engage in health-related research. This program is not designed for investigators seeking to prove their research potential.

The proposed study must be full-time and must include the conduct of research with supervision or other opportunity for guidance appropriate to the applicant background and objective. Senior fellowship support may be requested for a period of up to 2 years.

* * * * *

Please use the following general guidelines when preparing written comments on senior fellowship applications assigned to you for review.

CANDIDATE. Describe and evaluate the candidate's research competence through an assessment of academic background, pertinent awards and honors, prior research experience, prior professional training, publications, and reference reports.

TRAINING RESOURCES AND ENVIRONMENT. Assess the quality of the training resource and environment, especially the suitability of the sponsor and department. Describe the additional training and discuss its relationship to the candidates' background and future objectives.

Foreign Training. Describe the scientific advantages of the foreign training as compared to training available domestically. If comparable training is available domestically, mention specific sites.

RESEARCH PROPOSAL. Summarize the research proposal and briefly evaluate its strengths and weaknesses. Assess the training value of the proposal and comment on its relationship to the sponsor's research effort.

Involvement of Human Subjects.

Exemptions Claimed. Evaluate the appropriateness of the claimed exemptions.

or

No Exemptions Claimed. Assess the appropriateness of the subject population. Explain any potential physical, psychological, social,

or legal risks to individuals who are participating as subjects in research, development, or related activities. Describe the procedures for protecting against or minimizing such risks, and discuss whether the risks are reasonable in relation to the anticipated benefits to subjects and the importance of the knowledge that may reasonably be expected to result. Assess the adequacy of the consent procedures.

Animal Welfare. If vertebrate animals are to be used in the project, discuss the appropriateness of the choice of species and numbers involved, and the justification for their use. Assess whether the animals will receive proper care and maintenance, and will not suffer unnecessary discomfort, pain, or injury. Special attention should be provided when the proposed research involves dogs, cats, nonhuman primates, or large numbers of animals.

Hazardous Materials and Procedures. Describe any potentially hazardous materials and procedures and whether the protection to be provided will be adequate.

SUMMARY AND RECOMMENDATION. Provide an overall evaluation of the strengths and weaknesses of the application and a recommendation of approval, disapproval, or deferral. If your recommendation is for approval, discuss the appropriateness of the requested length of support.

* * * * *

NOTE. Under the Privacy Act of 1974, candidates may have access, upon request, to documents generated during the review of their grant applications. You do not have to sign written comments, and your comments will not be retained after being incorporated into the summary statement. In the event that your comments must be made available to the candidate, you will be promptly notified by NIH staff.

REVIEW GROUP MEMBERS' ORIENTATION
SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

SMALL BUSINESS INNOVATION DEVELOPMENT ACT OF 1982 (P.L. 97-219)

P.L. 97-219, an amendment to the Small Business Act, requires the agencies of the Public Health Service (PHS) and certain other federal agencies to set aside a specified amount of their research and development (R&D) budgets for a Small Business Innovation Research (SBIR) Program. The purpose of this legislation is to:

- o stimulate technological innovation;
- o use small business to meet federal research and development needs;
- o increase private sector commercialization of innovations derived from federal research and development; and
- o foster and encourage participation by minority and disadvantaged persons in technological innovation.

The Small Business Innovation Development Act is intended to promote technological innovation within the American small business community and thereby create jobs, augment industrial productivity, increase competition, and spur economic growth.

THE PHS SBIR PROGRAM

For purposes of the SBIR Program, "research" or "research and development" (R&D) is defined as any activity which is: (a) a systematic, intensive study directed toward greater knowledge or understanding of the subject studied; (b) a systematic study directed specifically toward applying new knowledge to meet a recognized need; or (c) a systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development and improvement of prototypes and new processes to meet specific requirements.

The SBIR Program consists of the following three phases:

Phase I (R43): establishes the technical merit and feasibility of proposed research or R&D efforts that may ultimately lead to commercial products or services, and to determine the quality of performance of the small business awardee organization. Awards normally may not exceed \$50,000 (both direct and indirect costs) for a period normally not to exceed 6 months.

Phase II (R44): is to continue the research or R&D efforts initiated in Phase I which are likely to result in commercial products or services. Funding shall be based on the results of Phase I and the scientific and technical merit of the Phase II applications. Only Phase I awardees are eligible to apply for Phase II funding. Phase II awards normally may

not exceed \$500,000 (including both direct and indirect costs) for a period normally not to exceed 2 years.

Phase III: small businesses are to pursue with private capital the commercialization of the results of R&D funded in Phases I and II, or a Federal agency may award non-SBIR funded contracts for products or processes intended for use by the U.S. Government.

The following definitions of approval, disapproval and deferral will be used in the review of SBIR applications.

Approval: the application is of sufficient merit to be worthy of support based on the relevant review criteria. The vote for approval is equivalent to a recommendation that a grant be awarded provided sufficient funds are available.

Disapproval: the application is not of sufficient merit, or for other stated reasons (e.g., gravely hazardous or unethical procedures are involved), not worthy of support.

Deferral (applicable only to Phase II): the application may be deferred because of insufficient information to make a recommendation, for additional information or for a project site visit.

REVIEW OF PHASE I -

- o Since Phase I is to be a technical feasibility study, reviewers should not expect the application to provide data establishing feasibility of the project.
- o The evaluation criteria for Phase I review are as follows:
 - (1) Scientific and technical merit of the proposed approach;
 - (2) Qualifications of the principal investigator, supporting staff and consultants;
 - (3) Appropriateness of the budget requested;
 - (4) Adequacy and suitability of the facilities and research environment.
 - (5) For administrative use by NIH staff, please comment on the potential of the proposed research for commercial application.
- o The recommended action and the priority score will be based on an assessment of the scientific and technical merit of the application, but not on commercial potential.

- o In accordance with the Code of Federal Regulations, Title 42, Part 52, the principal investigator of a research project is "a single individual, designated by the grantee in the grant application and approved by the Secretary, who is responsible for the scientific and technical direction of the project." "Consultants" from academia cannot provide the scientific/technical direction for the project unless they are in the employ of the small business more than one-half time.
- o The 6-month budget will be examined and modified, if necessary. Amounts over the prescribed level will be handled by BID staff.
- o The resources and environment will be assessed.
- o If human subjects are involved, the adequacy of human subject protection will be assessed.
- o The authenticity and structure of the small business, the relationship of the key personnel to the small business and to other institutions, etc., are administrative matters. Comments will be appropriate in Administrative Notes, but these factors will not affect the scientific and technical merit evaluation.

REVIEW OF PHASE II

- o The definitions of approval, disapproval and deferral, given above, will be used.
- o The evaluation criteria for Phase II review are as follows:
 - (1) Degree to which the Phase I objectives were met and feasibility demonstrated.
 - (2) Scientific, technical, and/or public health importance of the problem or opportunity and anticipated benefits if Phase II research is successful.
 - (3) The adequacy of the Phase II objectives and methodology for addressing the problem or opportunity.
 - (4) The technical merit of the proposed research with special emphasis on innovation and/or originality.
 - (5) The qualifications of the principal investigator, supporting staff and consultants.
 - (6) The reasonableness of the budget requested for the work proposed.
 - (7) The adequacy and suitability of the facilities and research environment.

- o For administrative use by the NIH staff, please comment on:
 - The potential of the proposed research for commercial application.
- o The recommended action and the priority score will be based on an assessment of the results of the Phase I effort (as reflected in the final report) and the technical merit of the proposed Phase II research. Expectations of Phase I results should take into consideration the brevity of the Phase I grant period (6 months).
- o In accordance with the Code of Federal Regulations, Title 42, Part 52, the principal investigator of a research project is "a single individual, designated by the grantee in the grant application and approved by the Secretary, who is responsible for the scientific and technical direction of the project." "Consultants" from academia cannot provide the scientific/technical direction for the project unless they are in the employ of the small business more than one-half time.
- o The budget will be examined and modified, if necessary. Amounts and term of support over the prescribed level will be handled by BID staff.
- o If a study section believes that a Phase II project can be accomplished within a shorter period of time than proposed by the principal investigator, it may reduce the amount and period of support accordingly.
- o The resources and environment will be assessed.
- o Biohazards should be assessed.
- o If human subjects are involved, the adequacy of human subject protection will be assessed.
- o If animals are involved, the adequacy of the care and use of animals will be assessed.
- o The authenticity and structure of the small business, the relationship of the key personnel to the small business and to other institutions, etc., are administrative matters. Comments will be appropriate in Administrative Notes, but these factors will not affect the scientific merit evaluation.

CONFIDENTIALITY

All materials pertinent to the applications being reviewed are privileged communications prepared for use only by consultants and NIH staff and should not be shown to or discussed with other individuals. Consultants are requested to leave all review materials with the Executive Secretary at the conclusion of the review meeting.

Under no circumstances should consultants advise either investigators or their organizations or anyone else of recommendations or discuss the review proceedings with them. The investigator may be led into unwise actions on the basis of premature or erroneous information. Such advice also represents an unfair intrusion into the privileged nature of the proceedings and invades the privacy of applicants as well as consultants serving on review committees. A breach of confidentiality could (1) result in disclosure of trade secrets or other proprietary information (commercial as well as financial) and (2) deter qualified consultants from serving on review committees and inhibit those who do so from engaging in free and full discussion of recommendations.

CONFLICT OF INTEREST

A. A study section may not review an application in which:

1. One of its members, or the member's spouse, parent, or child, is the principal investigator or is listed on the budget page in any capacity;
2. One of its members is an owner or officer in the organization submitting the application; or
3. A member's close professional associate is the principal investigator or is responsible for conducting any portion of the planned research. The exact determination of how close the professional association must be to be considered a conflict of interest is a matter of judgment. The decision will be based on the recency, frequency, and strength of the working relationship between the member and the associate, as reflected, for example, in publications.

B. Reviewers must leave the room during the review of an application:

1. Involving their own organization. In the case of organizations with multiple sites geographically separated, the term "own organization" includes the entire system in which the member is an employee, or with which the member is negotiating or has any arrangement concerning prospective employment;
2. Submitted by an organization in which the member has a financial interest. This includes holding stock in or serving as a consultant for the organization; or
3. If the member's presence would give the appearance of a conflict of interest.

COMMUNICATIONS WITH INVESTIGATORS

There should be no direct communications between members of review groups and investigators. Reviewers' requests for additional information and telephone inquiries or correspondence should be directed to the executive secretary who will handle all such communications.

GUIDE FOR ASSIGNED REVIEWERS' PRELIMINARY COMMENTS ON SMALL BUSINESS INNOVATION RESEARCH GRANT APPLICATIONS

Please use the following guidelines when preparing written comments on SBIR applications.

DESCRIPTION. Clearly and concisely describe the objectives and procedures of the application. Use the abstract on page 2 of the application unless inappropriate. Do not make evaluative statements in this section.

CRITIQUE. Scientific Merit. Do not repeat the description in this section. Provide a comprehensive evaluation of the strengths and weaknesses of the application, including the significance and innovativeness of the proposed research, the rationale for the study, the logic of the aims, and the adequacy of the procedures. For Phase II applications, assess the degree to which Phase I objectives were met and feasibility demonstrated.

INVESTIGATORS. Assess the competence of the principal investigator(s) and key staff to conduct the proposed research, including their academic qualifications, research experiences, productivity, and any special attributes.

RESOURCES AND ENVIRONMENT. Discuss any special aspects of the facilities and equipment. Comment on the availability of essential laboratory, clinical, animal, computer, or other resources.

BUDGET. Determine whether all items of the budget are realistic and justified in terms of the aims and methods. Provide adequate justification for each suggested modification in amount.

OTHER CONSIDERATIONS

Overlap. Identify any apparent scientific or budgetary overlap with active or pending support.

Potential Commercial Application (if applicable). Comment on the potential of the proposed research for commercial application.

Involvement of Human Subjects

Exemptions Claimed. Evaluate the appropriateness of the claimed exemptions
or

No Exemptions Claimed. Assess the appropriateness of the subject population. Explain any potential physical, psychological, social, or legal risks to individuals who are participating as subjects in research, development, or related activities. Describe the procedures for protecting against or minimizing such risks, and discuss whether the risks are reasonable in relation to the anticipated benefits to subjects and the importance of the knowledge that may reasonably be

expected to result. Assess the adequacy of the consent procedures.

Animal Welfare. If vertebrate animals are to be used in the project, discuss the appropriateness of the choice of species and numbers involved, and the justification for their use. Assess whether the animals will receive proper care and maintenance, and will not suffer unnecessary discomfort, pain, or injury.

Hazardous Materials and Procedures. Describe any potentially hazardous materials and procedures and whether the proposed protection provided by the investigator will be adequate.

SUMMARY AND RECOMMENDATION. Provide an overall evaluation of the strengths and weaknesses of the application and a recommendation of approval or disapproval.

NOTE: Under the Privacy Act of 1974, principal investigators may have access, upon request, to documents generated during the review of their grant applications. You do not have to sign written comments, and your comments will be destroyed after being incorporated into the summary statement. In the event that your comments must be made available to a principal investigator, you will be promptly notified by NIH staff.

REVIEW PROCEDURES FOR INITIAL REVIEW GROUP MEETINGS

REVIEW PROCEDURES

The initial review group (IRG) evaluates the scientific merit of each grant application according to specific criteria. The principal criteria for the initial review of research project grant applications 1 based on the Public Health Service (PHS) Scientific Peer Review Regulations, include:

- o scientific, technical, or medical significance and originality of the goals of the proposed research;
- o appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research;
- o qualifications and research experience of the principal investigator and staff, particularly but not exclusively in the area of the proposed research;
- o availability of resources necessary to the research;
- o the proposed budget and duration in relation to the proposed research; and
- o where an application involves activities that could have an adverse effect on humans, animals, or the environment, the adequacy of the proposed means for protecting against or minimizing such effects. (See pages 2 to 4.)

In addition, for renewal and supplemental applications, preliminary data and/or progress to date must be evaluated. For revised applications, the changes must be appraised.

During the meeting, the Chairperson of the IRG, following an agenda prepared by the Executive Secretary, introduces each application, calls upon the individuals assigned by the Executive Secretary to present their written comments, and invites discussion. At an appropriate time, the Chairperson requests a motion on the application. The possible motions can be for approval, disapproval, or deferral. It should be noted that only regularly appointed members may make motions, vote, and assign priority ratings.

- o Approval: The application is of sufficient merit to be worthy of support based on the appropriate review criteria. A vote for approval is equivalent to a recommendation that a grant be awarded provided sufficient funds are available. A priority rating is required.
- o Disapproval: The application is not of sufficient merit to be worthy of support. Disapproval may also be recommended when gravely hazardous or unethical procedures are involved, or when no funds can be recommended, as in the case of a supplement deemed to be unnecessary. No priority rating is assigned.

- o Deferral: The IRG cannot make a recommendation without additional information. This information may be obtained by a project site visit or by the submission of additional material by the applicant. Deferred applications are usually reviewed again at the next IRG meeting.

After a motion of approval, disapproval, or deferral has been seconded, the Chairperson asks for any further discussion. The Chairperson then calls for the question, and the regularly appointed IRG members vote on the motion. The recommendation of the IRG for each application is made by majority vote.

The budget must be discussed before a priority is assigned. The budget recommendation, which can be for the time and amount requested or for an adjusted time and amount, should include not only the first year but also each subsequent year.

Split Vote

If two or more of the regularly appointed members disagree with the recommendation of the IRG, the dissenting members must prepare a written minority report. For any recommendation obtained by a split vote, the full action of the committee must be recorded: number of votes for the motion, number of votes against the motion, and the number of abstentions. Members are encouraged not to abstain. However, if a member is unable to assess the merit of an application without additional information, as evidenced by his/her prior discussion or recommendation for deferral, that member should abstain from voting on a motion for approval or disapproval.

Priority Rating

For each application that has been recommended for approval, each regularly appointed member who votes for or against the motion records a numerical rating that reflects the member's opinion of the merit of the application. The numerical rating ranges from 1.0 (the most meritorious) to 5.0 (the least meritorious) with increments of 0.1. The priority rating pertains to the recommended, not the requested, budget and duration of support. Abstaining members, i.e., those who do not vote on the motion, do not assign a numerical rating, and are not counted in calculating the average of the individual ratings.

If any member who votes for or against a motion for approval does not assign a priority rating, that member's action shall be recorded as an abstention.

OTHER CONSIDERATIONS

Overlap. Reviewers will identify any apparent scientific or budgetary overlap with active, pending, or planned support.

Foreign Organizations. The proposal is evaluated in terms of any special opportunities for furthering research programs through the use of special talents, resources (human subjects, animals, diseases, equipment or technologies), populations or environmental conditions in the applicant country which are not readily available in the United States or which provide augmentation of existing United States resources. In addition, notice is taken whether similar research is being done in the United States and whether there is a need for additional research in the area of the proposal. In the

case of a domestic application with a significant foreign component, the same review criteria are applied.

Research Involving Human Subjects

Applicant organizations have the primary responsibility for safeguarding the rights and welfare of individuals who participate as subjects in research activities supported by the NIH. However, the NIH also relies on its IRGs and National Advisory Councils or Boards to evaluate all applications and proposals involving human subjects for compliance with the Department of Health and Human Services human subject regulations.

The regulations define "human subject" as a "living individual about whom an investigator obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable state and local law and is not directly regulated by the Federal human subject regulations.

The Department will fund research covered by these regulations only if the institution has filed an assurance with the NIH Office for Protection from Research Risks and has certified that the research has been approved by an Institutional Review Board (IRB) and is subject to continuing review by the IRB. When research involves only minimal risk and meets certain other conditions, the IRB may waive the requirement for obtaining informed consent. In addition, certain research that poses little or no risk to human subjects is exempt from IRB review and approval. In such cases, however, adherence to ethical standards and pertinent laws is still required.

The review by the IRG is expected to reflect existing codes adopted by disciplines relevant to the research or the collective standards of the professions represented by the membership. The evaluation by IRG members is to take into consideration any potential risks to the subjects, the procedures for protecting against or minimizing these risks, the potential benefits of the proposed research to the subjects and in relation to the importance of the knowledge that may reasonably be expected to result. Based on this evaluation, the IRG may recommend:

- o approval without restrictions;
- o approval with recorded comments or expressions of concern to be communicated to the institution and principal investigator;
- o approval with limitations on the scope of the work proposed, the imposition of restrictions, or the elimination of objectionable procedures involving human subjects;
- o deferral for clarification; or
- o disapproval if the research risks are sufficiently serious and protection against the risks so inadequate as to consider the entire application unacceptable.

Any comments or concerns that IRG members may wish to express regarding the adequacy of protections afforded human subjects will be discussed in a Special

Note in the summary statement. No awards will be made until all expressed concerns about human subjects have been resolved to the satisfaction of the NIH. Specific concerns and policy interpretation requests may be addressed to the Office for Protection from Research Risks, which is responsible for the administration and interpretation of DHHS policy and regulations for the protection of human subjects of research.

Research Involving Vertebrate Animals

Although the recipient institution and investigator bear the major responsibility for the proper care and use of animals, NIH staff, IRGs, and Councils share this responsibility. Care and use of vertebrate animals in research must conform to applicable law and Public Health Service policy, especially the Principles for Use of Animals. These principles can be summarized as two broad rules.

- o The project should be worthwhile and justified on the basis of anticipated results for the good of society and the contribution to knowledge, and the work should be planned and performed by qualified scientists.
- o Animals are to receive proper care and treatment, and should not be confined, restrained, transported, cared for, and used in experimental procedures in a manner to cause any unnecessary discomfort, pain, or injury.

Any comments or concerns that IRG members may wish to express regarding the appropriateness of the choice of species and numbers involved, the justification for their use, and the care and maintenance of vertebrate animals used in the project will be discussed in a Special Note on the summary statement. Questions may be directed to the Office for Protection from Research Risks. No award will be made unless the applicant institution has given the NIH Office for Protection from Research Risks an acceptable assurance of compliance with the PHS policy and all concerns or questions raised by the IRG have been resolved to the satisfaction of the NIH.

Hazardous Research Materials and Methods

The investigator and the sponsoring institution are responsible for protecting the environment and research personnel from hazardous conditions. As with research involving human subjects, reviewers are expected to apply the collective standards of the professions represented within the IRG in identifying potential hazards, such as inappropriate handling of oncogenic viruses, chemical carcinogens, infectious agents, radioactive or explosive materials, or recombinant DNA.

If applications pose special hazards, these hazards will be identified and any concerns about the adequacy of safety procedures highlighted as a Special Note on the summary statement. No awards will be made until all concerns about hazardous procedures or conditions have been resolved to the satisfaction of the NIH.

AVOIDING CONFLICTS OF INTEREST DURING IRG MEETINGS

At the beginning of each meeting, the executive secretary orients the members by explaining the NIH conflict-of-interest policy. A member must leave the room when an application submitted by his/her own organization ^{or} is being discussed or when the member, his/her immediate family, or close professional

associate(s) ^{3/} has a financial interest (indicated on Form 474), even if no significant involvement is apparent in the proposal being considered. This would include the member's availability at the principal investigator's institution for discussions; being a provider of services, cell lines, reagents, or other materials; or writing of a letter of reference. In these cases, the member must be absent from the room during the review. Members are also urged to avoid any actions that might give the appearance that a conflict of interest exists, even though he or she believes there may not be an actual conflict of interest. Thus for example, a member should not participate in the deliberations and actions on any application from a recent student, a recent teacher, or a close personal friend. Judgment must be applied on the question of recency, frequency and strength of the working relationship between the member and the principal investigator as reflected for example, in publications. Another example might be an application from a scientist with whom the member has had longstanding differences which could reasonably be viewed as affecting the member's objectivity. However, if the executive secretary determines that the member can be objective, then a balanced point of view for the review is appropriate.

A reviewer must leave the room during discussion of an application if he/she is a member of, or has a financial interest in the for-profit organization submitting the application. This includes ownership of stock in, or being a consultant for the for-profit organization. A reviewer should also leave the room during discussion of an application if being present would give the appearance of a conflict of interest. Examples would be, an application from a for-profit organization that provides substantial financial funding to the reviewer's organization or laboratory, or from a for-profit organization that is in commercial competition with the reviewer's organization.

At the end of the IRG meeting, the Executive Secretary obtains written certification from all members that they have not participated in any reviews of applications when their presence would have constituted a real or apparent conflict of interest. In addition, each study section keeps a log, prepared by the Grants Assistant and maintained in the study section office, of which members left the room and for what applications.

CONFIDENTIALITY

All materials pertinent to the applications being reviewed are privileged communications prepared for use only by consultants and NIH staff, and should not be shown to or discussed with other individuals. Review group members must not independently solicit opinions or reviews on particular applications or parts thereof from experts outside the pertinent initial review group. Members may, however, suggest scientists from whom the Executive Secretary may subsequently obtain advice. Consultants are requested to leave all review materials with the Executive Secretary at the conclusion of the review meeting.

Under no circumstances should consultants advise investigators, their organizations, or anyone else of recommendations or discuss the review proceedings with them. The investigator may be led into unwise actions on the basis of premature or erroneous information. Such advice also represents an unfair intrusion into the privileged nature of the proceedings and invades the privacy of fellow consultants serving on review committees and site visit teams. A breach of confidentiality could deter qualified consultants from serving on review committees and inhibit those who do from engaging in free and full discussion of recommendations.

August 1986

COMMUNICATIONS WITH INVESTIGATORS

Except during site visits, there should be no direct communications between consultants and investigators. Consultants' requests for additional information and telephone inquiries or correspondence from investigators should be directed to the Executive Secretary, who will handle all such communications.

FOOTNOTES

1/ The specific review criteria will vary with other types of applications such as the National Research Service Awards (fellowships), Research Career Development awards, or Small Business Innovation Research grants.

2/ The term "own organization" includes the entire system in which the member is an employee, consultant, officer, director, or trustee or has a financial interest; or with which the member is negotiating or has any arrangement concerning prospective employment. However, it has now been determined that the interest involved is too remote or too inconsequential to affect the integrity of a special Government employee's review of a funding application or contract proposal from one campus of one of the following multi-campus institutions, where the interest consists solely of employment as a faculty member (including Department Chairman) at a separate campus of the same multi-campus institution:

The University of Alabama system consisting of the University of Alabama, the University of Alabama in Birmingham, and the University of Alabama in Huntsville.

The campuses of the University of California.

The system consisting of Colorado State University, the University of Southern Colorado, and Fort Lewis College.

The Indiana University system consisting of eight universities on nine campuses, with the exception of the system-wide schools: the School of Business; the School of Dististry; the School of Medicine; the School of Nursing; and the School of Public and Environmental Affairs.

The University of Nebraska system consisting of the University of Nebraska—Lincoln, the University of Nebraska at Omaha, and the University of Nebraska Medical Center.

The campuses of the State University of New York.

The Oregon system of higher education consisting of the University of Oregon, Oregon State University, Oregon Health Sciences University, Portland State University, Western Oregon State College, Southern Oregon State College, Eastern Oregon State College, and the Oregon Institute of Technology.

The campuses of the University of Tennessee.

The separate universities comprising the University of Texas System.

The separate universities comprising the University of Wisconsin System.

c.f. Federal Register, April 25, 1986, Part 73 (Amended)

3/ Co-workers and other colleagues with whom members regularly co-author papers, consult, or otherwise closely relate. "Close professional associate" is the term NIH finds most appropriate to the word "partner" in the Federal conflict-of-interest laws and regulations.

SUMMARY STATEMENT WORKSHEET

PLEASE DOUBLE SPACE

APPLICATION NO. _____

PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR/CANDIDATE _____

ASSIGNMENT LIST

156



FIGURE 43

ADDITIONAL INFORMATION REQUEST LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

(Date)

Building :
Room :
(301) 496-

Re: (application number)

(inside address)

Dear Dr.

In order to facilitate the processing of your application which will be reviewed by the _____ Study Section in _____, 19____, please forward to me, as soon as possible, six (6) copies of the following information:

- ___ Please supply a description of the research supported by _____
- ___ Also please delineate any scientific or budgetary boundaries or overlaps with the present application.
- ___ Additional information regarding the use, care, and handling of animals. (see attachment)
- ___ A completed HEW-596 form (Human Subjects).
- ___ The 6 points answered for research involving human subjects (see instructions in application kit PHS 398)
- ___ A statement indicating all significant changes made in this amended application.
- ___ Other:

If you have any questions, please call me at 301-496-

Sincerely,

(Exec. Sec.'s name & degree)
Executive Secretary
Study Section
Division of Research Grants

FIGURE 43a

INFORMATION REQUEST FORM FOR RESEARCH
INVOLVING VERTEBRATE ANIMALS

Involvement of live, vertebrate animals for research purposes as described in your proposal (even if at no cost to your proposal and/or if performed at a secondary site) require the submission of the following information to complete your application. Unless received by _____ the review of your application will be deferred to the next review cycle.

- () Applications from institutions that do not have an approved Assurance on file with the Office for the Protection from Research Risks (OPRR), NIH, must contain a declaration that the institution will establish an Institutional Animal Care and Use Committee (IACUC) and submit an Assurance upon request by OPRR. See note.
- () Applications from institutions with approved Assurances must provide a letter of verification of the date of review by the IACUC signed by the authorized institutional official. See Note.
- () Complete discussion of the following points must be provided:
 - a. identification of the species and approximate number of animals to be used;
 - b. rationale for involving animals, and for the appropriateness of the species and number to be used;
 - c. a complete description of the proposed use of the animals;
 - d. assurance that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals;
 - e. a description of any euthanasia method to be used.

Note: The verification or declaration must come from your own institution even if the animal research is to be done at a secondary site.

THE NIH CONFLICT OF INTEREST POLICY AND CERTIFICATION

According to the NIH conflict-of-interest policy, an individual may not be involved in the review of an application submitted by his or her own organization, 1/ or when the reviewer or his or her immediate family, or close professional associate(s) 2/ has a financial interest even if no significant involvement is apparent in the proposal being considered. This would include the reviewer's availability at the principal investigator's institution for discussions; being a provider of services, cell lines, reagents, or other materials; or writing of a letter of reference. Reviewers are urged to avoid any actions that might give the appearance that a conflict of interest exists, even though he or she believes there may not be an actual conflict of interest. Thus, for example, you should not participate in the review of any application from a recent student, a recent teacher, or a close personal friend. Judgment must be applied on the question of recency, frequency and strength of the relationship between yourself and the principal investigator as reflected, for example, in publications and in the continuing nature of the relationship. Another example might be an application from a scientist with whom you have had longstanding differences which could reasonably be viewed as affecting your objectivity.

A reviewer may not evaluate an application if he or she is a member of, or has a financial interest in a for-profit organization submitting the application. This includes ownership of stock in, or being a consultant for the for-profit organization. If there is the appearance of a conflict of interest, for example, an application from a for-profit organization that provides substantial financial funding to your organization or laboratory, or from a for-profit organization that is in commercial competition with your organization, you should not be involved in the review.

When you complete your review, please sign the certification that you have not participated in the review of an application with which you have a real or apparent conflict of interest.

1/ The term "own organization" includes the entire system in which you are an employee, consultant, officer, director, or trustee or have a financial interest; or with which you are negotiating or have any arrangement concerning prospective employment.

2/ Co-workers and other colleagues with whom you regularly co-author papers, consult, or otherwise closely relate. "Close professional associate" is the term NIH finds most appropriate to the word "partner" in the Federal conflict-of-interest laws and regulations.

I have read the NIH policy statement on conflict of interest and hereby certify that I was not involved in the review of an application with which I am in real or apparent conflict of interest.

Signature

Name

Application No. for which outside opinion is provided _____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20201
Building :
Room :
(301) 498-

Re:

Re:

The enclosed application is scheduled for review at the Study Section meeting, It would be of considerable assistance to the Study Section in evaluating this application if you could give your opinion of the proposed project. Enclosed is the relevant Guide for reviewers' Comments.

Please forward your typed comments to me by so that they can be made available to reviewers before the meeting. Because of the confidential nature of review materials, the application and any accessory materials, should be disposed of in a confidential manner.

Attached is "The NIH Conflict of Interest Policy and Certification". Please read this statement outlining NIH policy regarding conflict of interest and return the signed form with your review in the enclosed envelope.

Under the Privacy Act of 1974, principal investigators may have access, upon request, to documents generated during the review of their grant application. You do not have to sign written comments, and your comments will not be retained after being incorporated into the summary statement. In the unlikely event that your comments must be made available to a principal investigator, you will be promptly notified by NIH staff.

Your contribution to the evaluation process is very much appreciated. If you have any questions, please call me collect.

Sincerely yours,

(NAME)
Executive Secretary
Study Section
Division of Research Grants

Enclosures

Chapter VII

PREPARATION FOR MEETINGS BY THE GRANTS ASSISTANT

A. PREPARATION OF WORKBOOKS: MAILING PROCEDURES

The Executive Secretary and Grants Assistant usually work together to develop a tentative mailing schedule as well as cut-off dates for requesting outside opinions and additional information. Such schedules depend on the time required for duplicating and distributing the additional information and the dates of the study section meeting.

The members' workbooks contain the applications and supporting material that will be needed at the study section meeting. Applications should be arranged by Institutes in alphabetical order. The applications within each Institute should be in numerical order. Members should not receive applications submitted by their own organizations. (See Chapter XV, Section A.)

The study section office may send members either complete workbooks or periodic mailings of applications and pertinent materials that will be later assembled into workbooks by the members. In either case, complete workbooks and the assignment list should be received by members about 4 weeks before the meeting--earlier if possible.

Mailings should not be postponed for late replies from applicants or outside reviewers; such material can be sent later.

1. Mailings

- a. Mailing to Assignees First, With Complete Workbooks Mailed Later. Some study sections send packages of applications with pertinent materials to assignees first, so that the assignees have their review applications as soon as possible. No later than 4 weeks before the meeting, complete workbooks are assembled and sent to all members, excluding any applications for which there is a conflict of interest.
- b. Periodic Mailing to All Members. In some study sections, applications and materials are mailed to members as soon as they are received, along with a partial assignment list. Periodically thereafter, additional information and applications with supporting materials are mailed until all have been distributed. A cut-off date for such mailings should be set, however, and material received after that date should be kept for distribution at the meeting.

A covering memo or mailing list should be sent with each mailing. A complete assignment list should be sent with the last mailing or as soon as all assignments are firm.

- c. Assignment Mailing. The following materials should be included in assignment mailings:

For Assignees:

- Applications and supporting materials (appendices, preprints, reprints, collaborative letters, reference letters*, etc.);
- Any additional information from the principal investigator;
- Revised budget pages;
- Outside opinions;
- Project site visit reports;
- Summary statements (for competing continuation applications);
- Previous application (for amended and supplemental applications);
- Forms on which to prepare comments (Figure 46);
- Covering memo, with general information about the meeting (Figure 47);
- Agenda (Figure 48);
- Guides for Reviewers' Preliminary Comments for each type of application (R01, K04, R29, F32, etc.);
- Review Procedures (See Chapter VI);
- The study section roster for the current meeting (Figure 49).

- d. Miscellaneous Items Sent With Mailings. In addition to the workbooks, study section members may receive the following items:

- Return postcards, so that they can notify the study section office that material was received and if material was missing; and
- Self-addressed business reply envelopes for return of written reviews.

- e. Workbook Mailings. This includes the complete book of applications to be reviewed except for conflicts.

2. Workbooks for Observers

Two workbooks of applications only for observers are to be available at the meeting and discarded at the end of the meeting. These books are not for Institute representatives' use during meetings, and a statement to this effect should be noted on the cover.

*Reference letters are required for fellowship and FIRST applications.

3. General Mailing Procedures

Small packages (up to 2 oz) are to be sent in regular NIH franked envelopes, with the address typed on a plain white label or on the envelope. Larger packages are to be sent in unfranked envelopes or in jiffy bags, with a standard mailing label affixed. These supplies can be obtained at the Self Service Store or from the Office Services Section, DRG. For extra large packages, boxes available from Office Services may be used (Figure 50).

Accordion folders may be used in assembling the applications into books. After the jiffy bags or boxes have been filled, the Grants Assistant attaches a completed franked label, closes and seals the packages, and then calls Office Services (496-9797) to have them picked up to be mailed.

B. FORMS OBTAINED FROM THE DRG COMPUTER SYSTEM

The following forms are necessary for the study section meeting. They may be obtained by accessing TSO on the computer. Instructions for obtaining the following documents are found in the User Resource Office.

1. Assignment List (Function #54, which is SSR - Simplified System for Reports)

To receive an accurate listing of applications assigned to a particular study section, the Grants Assistant should periodically order a computerized assignment list. Follow the instructions in SSR. This list, which comes in various formats, may be sent with each mailing to study section members. Various types of file labels may also be ordered with this list, which Grants Assistants use for filing and identifying additional information. Address labels for study section members are also ordered through this computer function.

2. Scoring Sheets (Function #71, which is IIS - IRG Interface System)

Computerized scoring sheets (Figure 51) are used by study sections for members (not ad hoc reviewers) to record their priority scores for each application. These scoring sheets should be requested from the computer by the Grants Assistant close to the meeting date (1 or 2 weeks prior to the meeting). When a study section requests scoring sheets, the computer workfiles can be updated and corrected with information on each application to be reviewed.

3. Administrative Data List (Function #71)

The Administrative Data List (Figure 52) is available only after ordering scoring sheets. At this time, the Grants Assistant should check the following items for accuracy on each application:

- Assignment number,
- Spelling of the investigator's name,

- Human Subject Code (HSC),
- Principal investigator's degree,
- Institution, city, and state,
- Beginning dates,
- Requested amounts, and
- Title of the project.

The title is limited to 53 spaces; if the maximum is exceeded, the Executive Secretary must shorten it. To insure the accuracy of the above information, enter all corrections in the computer system for updating, and order a new Administrative Data List to check that corrections have been made. The Administrative Data list may also be used by the Executive Secretary and Grants Assistant to record the budgets after they have been computed and to record actions taken by the study section during the meeting. This information is then entered into the IIS system after the study section meeting.

4. Worksheets, (Function #71)

At present some study sections are still using worksheets and so the worksheet section has been included in this handbook. The worksheet may be ordered when the scoring sheets are requested. (See Figure 53).

C. MATERIALS NEEDED DURING THE MEETING

Specific materials are gathered or prepared by the Grants Assistant prior to the meeting. Because so many items are involved, a suggested checklist follows, which can, of course, be changed to suit the individual study section.

1. Checklist

a. Members' Meeting Folders

- Additional materials received too late for mailing;
- Peer Review Notes (available in the Grants Inquiries Office, WB/449);
- Agenda (Figure 48);
- Assignment List (Figure 54);
- Copy of previous Study Section Minutes;
- Calendar;
- Roster (Figure 49);
- Review Procedures for Initial Review Group (IRG) Meetings (See Chapter VI, Optional);
- Seating Chart (Figure 55);
- Travel Reimbursement Form (Figures 56 and 57) and business reply envelope;
- Scoring Sheets (Figure 51).

b. Extra Supplies and Reference Materials

- Two extra copies of complete study section minutes;
- Copies of seating chart, agenda, roster and meeting list;
- Name plates (optional);

- Two extra workbooks for observers;
- Office supplies (scissors, stapler and staples, stapler remover, tape, string, mailing labels, rubber bands, paper clips, and extra boxes or bags for trash);
- Schedules of Council meetings (optional);
- Schedules of study section meetings (optional);
- Shorthand notebook;
- Sign in sheet for visitors.

c. Additional Items When the Meeting is Off the Reservation

- Large lined pads;
- Mailing labels (franked), envelopes, and jiffy bags for out-of-town meetings;
- Pencils;
- Phone book.

NOTE: For out-of-town meetings, there are no name plates. (Put seating chart on the door.)

d. Extra Activities Before the Meeting

- Remind the Executive Secretary to have the comptime request completed;
- Order parking permits if the meeting is on the reservation or at certain hotels;
- Type Certification of No Conflict of Interest forms (See Chapter XI);
- Fill in Chronological Record of Claims for Travel Reimbursement for Consultants (Figure 58) to be completed as travel claims are processed after the meeting.

2. Seating Chart

The Chairperson sits next to the Executive Secretary, while the Grants Assistant is seated either near the Executive Secretary or on the other side of the Chairperson. There are no standard rules governing the seating arrangements for study section members.

Seating arrangements should be made so that observers can identify members. Also a seating chart should be provided showing the conference table and the location of the staff and study section members. Extra copies of this chart should be available for visitors.

3. Agenda

The Executive Secretary prepares the agenda for the study section meeting, which normally includes the introduction of new members and pertinent reports followed by the review of applications (Figure 48).

Part of the meeting may be "open to the public", but most of the meeting, during application review, is closed to the public.

- Human Subject Code (HSC),
- Principal investigator's degree,
- Institution, city, and state,
- Beginning dates,
- Requested amounts, and
- Title of the project.

The title is limited to 53 spaces; if the maximum is exceeded, the Executive Secretary must shorten it. To insure the accuracy of the above information, enter all corrections in the computer system for updating, and order a new Administrative Data List to check that corrections have been made. The Administrative Data list may also be used by the Executive Secretary and Grants Assistant to record the budgets after they have been computed and to record actions taken by the study section during the meeting. This information is then entered into the IIS system after the study section meeting.

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- Peer Review Notes (available in the Grants Inquiries Office, WB/449);
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- Assignment List (Figure 54);
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- Seating Chart (Figure 55);
- Travel Reimbursement Form (Figures 56 and 57) and business reply envelope;
- Scoring Sheets (Figure 51).

b. Extra Supplies and Reference Materials

- Two extra copies of complete study section minutes;
- Copies of seating chart, agenda, roster and meeting list;
- Name plates (optional);

- Two extra workbooks for observers;
- Office supplies (scissors, stapler and staples, stapler remover, tape, string, mailing labels, rubber bands, paper clips, and extra boxes or bags for trash);
- Schedules of Council meetings (optional);
- Schedules of study section meetings (optional);
- Shorthand notebook;
- Sign in sheet for visitors.

c. Additional Items When the Meeting is Off the Reservation

- Large lined pads;
- Mailing labels (franked), envelopes, and jiffy bags for out-of-town meetings;
- Pencils;
- Phone book.

NOTE: For out-of-town meetings, there are no name plates. (Put seating chart on the door.)

d. Extra Activities Before the Meeting

- Remind the Executive Secretary to have the comptime request completed;
- Order parking permits if the meeting is on the reservation or at certain hotels;
- Type Certification of No Conflict of Interest forms (See Chapter XI);
- Fill in Chronological Record of Claims for Travel Reimbursement for Consultants (Figure 58) to be completed as travel claims are processed after the meeting.

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Seating arrangements should be made so that observers can identify members. Also a seating chart should be provided showing the conference table and the location of the staff and study section members. Extra copies of this chart should be available for visitors.

3. Agenda

The Executive Secretary prepares the agenda for the study section meeting, which normally includes the introduction of new members and pertinent reports followed by the review of applications (Figure 48).

Part of the meeting may be "open to the public", but most of the meeting, during application review, is closed to the public.

Study section agendas are now submitted to the User Resource Office no later than two weeks before a meeting to be put into the computer and thereby available to all Institutes. Follow instructions obtained from the User Resource Office.

The agenda should be duplicated in sufficient quantities for distribution to all study section members and for visitors at the meeting. It should also be sent to the appropriate Section Chief.

During the meeting days, the agenda, with a contact phone number, should be posted on the study section hall office door.

4. Rosters

Rosters (Figure 49) are completed by following instructions from the User Resource Office. The Chairperson is listed first, then the members in alphabetical order, with the Executive Secretary last. The Grants Assistant is optional. The roster is submitted to the User Resource Office to be available to all Institutes through the computer.

D. TRANSPORTATION OF MATERIALS TO AND FROM MEETING SITE

1. Local Meetings (NIH, Bethesda, or Washington)

Cardboard boxes for packing study section meeting materials can be obtained from the Self Service Store or from the Office Services Section.

Grants Assistants should make arrangements for transporting material about 3 days before the meeting. Transportation (496-4380) will need to know how much and what kinds of material are to be moved, when they should be picked up, where they should be taken, and the DRG CAN number. At the same time, Transportation can be informed when to pick up and return materials to the study section office.

2. Out-of-Town Meetings

The NIH Transportation Section cannot deliver material out of town. Therefore, the Grants Assistant should pack materials in boxes and prepare labels, after which the Office Services Section will have the materials picked up and sent via parcel post or by a Government Bill of Lading (Figure 59) to the meeting site. These packages should be sent at least 2 weeks before the meeting in order to ensure delivery. Additional materials can be sent later by postal check with the Mail Room for mailing instructions.

stant must make arrangements for someone at the receive and store the materials. This person can be action member or a staff member of the hotel where be held.

All material mailed in advance of the meeting and addressed to the Executive Secretary, Grants Assistant, or study section member should be marked "HOLD FOR ARRIVAL on (DATE)."

3. Hand Carried Materials

Scoring sheets, reviews and other essential items, including correspondence regarding room reservations, should be carried by the Grants Assistant or the Executive Secretary to the study section meeting.

NUMBER: _____

REVIEWERS: _____

NAME: _____

TO THE TYPIST: PLEASE DOUBLE SPACE AND USE PLAIN SHEET FOR CONTINUATION PAGES AND IDENTIFY WITH GRANT NUMBER.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health**Memorandum**

Date August 22, 1986

From John L. Meyer, Ph.D.
Executive Secretary, PTHA

Subject Review Meeting, October 15-17, 1986

To Members and Special Reviewers
Pathology A Study Section

The enclosed research and "First" award grant applications have been assigned to this study section for review at the October 1986 meeting in preparation for consideration by the Institute Advisory Councils during January 1987. The workload for this meeting is estimated to be 91 applications.

The study section meeting will take place at the Chevy Chase Holiday Inn, Chevy Chase, Maryland, 20815. The telephone number at the hotel is: (301) 656-1500. The meeting will begin at 8:00 a.m. on Wednesday, October 15, 1986. Reservations have been made for each of you at the Chevy Chase Holiday Inn; if you wish to make other arrangements, please let us know so that your reservation can be cancelled. For late arrival (after 6:00 p.m.) please call the hotel and give a credit card number or send a night's deposit. The price quoted for single rooms is \$58.00 plus tax. If you prefer to take the Metro the hotel is located near the Friendship Heights stop.

In addition to the applications, reprints, appendices and supplementary material already sent, I call your attention to several other enclosed documents relating to application review. These will be particularly helpful to those new to the review process. Please note the instructions regarding the use of animals.

Assignments: Each of you has been designated as one of two primary reviewers on a number of applications. It will be necessary for you to prepare written comments on each assigned application, following the appropriate format, for presentation and discussion at the study section meeting. If you have been designated as the first reviewer, please write a full evaluation, i.e., Description, Critique, Investigator, Resources/Environment, Budget, and Recommendation. If you are the second reviewer, you need not write a Description section.

The third person identified on the form has been designated as a "reader." The "reader" should be prepared to participate in the discussion. Written comments by the "reader" are optional but would be appreciated, particularly as they relate to strengths and weaknesses.

The purpose of the Description is to convey to the other members the essence of the research proposed and should not be excessively detailed. One page or less will be sufficient except in unusual circumstances. (The actual Summary Statement Description is prepared from the

Continued

investigators abstract.) Similarly, the Critique portion of your review, although the most important aspect of your analysis, should be precise and to the point. Excessive detail, especially regarding methodological problems, should be avoided unless you feel it is essential to the review. It is important that each application receive a thorough examination by the Study Section but because of the heavy workload generally assigned to Pathology A, the committee must be prepared to work efficiently. The Investigator section should emphasize relevant training and experience. Undergraduate and graduate degrees are not as important. This section also should be concise. The only area in which I almost always need additional detail is the budget reduction justification. This is perhaps the most common cause for rebuttal by investigators and the Institutes are becoming increasingly sympathetic to their concerns, particularly the number of years recommended. Unless I receive a justification for each item to be deleted, it will almost certainly be reinstated by Council.

For members not familiar with the general procedures of Pathology A, it is important to emphasize that both first and second reviewers have equal responsibilities for thorough reviews of assigned applications. Equal weight is given to each in the preparation of Summary Statements. In the presentation of their reviews to the Study Section, however, the second reviewer should be prepared to only discuss those issues which were not raised by the first reviewer or in which there is a difference of opinion. Similarly, the reader should only add missing elements to the discussion. I will, however, attempt to incorporate all points raised in the discussion, either from assigned reviewers, or other interested members of the Study Section.

An issue that surfaced at previous meetings was that it was sometimes difficult for members of the panel that were not assigned a particular application to gain the sense of a reviewer's opinion if the review was read verbatim from the printed copy. It was suggested that the attention of the entire Study Section would be improved if the assigned reviewers summarized, in a more narrative style, the important positive and negative aspects of the application. More importantly perhaps, this would also leave more time for discussion of the applications by interested members of the Study Section. I would still need the written copy for the purpose of preparing the Summary Statements but I believe the consensus of the group felt that the level of interest for each application would be considerably improved, resulting in a better review of each application with interaction of more members of the Study Section, if these suggestions are followed. Let's try to implement this slight change in our review procedure, and still be consistent with your own style of grant review, at the upcoming meeting.

A final point I would like to make in this regard is that, as many of you surely know, institutional administrators often use the Summary Statements to make tenure and promotional decisions. Although your written (and verbal) comments should accurately reflect your appraisal of the proposed research, the best interests of the investigators should also be kept in mind. Remember critique implies both positive and negative evaluations.

Continued



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health**Memorandum**

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The enclosed research and "First" award grant applications have been assigned to this study section for review at the October 1986 meeting in preparation for consideration by the Institute Advisory Councils during January 1987. The workload for this meeting is estimated to be 91 applications.

The study section meeting will take place at the Chevy Chase Holiday Inn, Chevy Chase, Maryland, 20815. The telephone number at the hotel is: (301) 656-1500. The meeting will begin at 8:00 a.m. on Wednesday, October 15, 1986. Reservations have been made for each of you at the Chevy Chase Holiday Inn; if you wish to make other arrangements, please let us know so that your reservation can be cancelled. For late arrival (after 6:00 p.m.) please call the hotel and give a credit card number or send a night's deposit. The price quoted for single rooms is \$58.00 plus tax. If you prefer to take the Metro the hotel is located near the Friendship Heights stop.

In addition to the applications, reprints, appendices and supplementary material already sent, I call your attention to several other enclosed documents relating to application review. These will be particularly helpful to those new to the review process. Please note the instructions regarding the use of animals.

Assignments: Each of you has been designated as one of two primary reviewers on a number of applications. It will be necessary for you to prepare written comments on each assigned application, following the appropriate format, for presentation and discussion at the study section meeting. If you have been designated as the first reviewer, please write a full evaluation, i.e., Description, Critique, Investigator, Resources/Environment, Budget, and Recommendation. If you are the second reviewer, you need not write a Description section.

The third person identified on the form has been designated as a "reader." The "reader" should be prepared to participate in the discussion. Written comments by the "reader" are optional but would be appreciated, particularly as they relate to strengths and weaknesses.

The purpose of the Description is to convey to the other members the essence of the research proposed and should not be excessively detailed. One page or less will be sufficient except in unusual circumstances. (The actual Summary Statement Description is prepared from the

investigators abstract.) Similarly, the Critique portion of your review, although the most important aspect of your analysis, should be precise and to the point. Excessive detail, especially regarding methodological problems, should be avoided unless you feel it is essential to the review. It is important that each application receive a thorough examination by the Study Section but because of the heavy workload generally assigned to Pathology A, the committee must be prepared to work efficiently. The Investigator section should emphasize relevant training and experience. Undergraduate and graduate degrees are not as important. This section also should be concise. The only area in which I almost always need additional detail is the budget reduction justification. This is perhaps the most common cause for rebuttal by investigators and the Institutes are becoming increasingly sympathetic to their concerns, particularly the number of years recommended. Unless I receive a justification for each item to be deleted, it will almost certainly be reinstated by Council.

For members not familiar with the general procedures of Pathology A, it is important to emphasize that both first and second reviewers have equal responsibilities for thorough reviews of assigned applications. Equal weight is given to each in the preparation of Summary Statements. In the presentation of their reviews to the Study Section, however, the second reviewer should be prepared to only discuss those issues which were not raised by the first reviewer or in which there is a difference of opinion. Similarly, the reader should only add missing elements to the discussion. I will, however, attempt to incorporate all points raised in the discussion, either from assigned reviewers, or other interested members of the Study Section.

An issue that surfaced at previous meetings was that it was sometimes difficult for members of the panel that were not assigned a particular application to gain the sense of a reviewers opinion if the review was read verbatim from the printed copy. It was suggested that the attention of the entire Study Section would be improved if the assigned reviewers summarized, in a more narrative style, the important positive and negative aspects of the application. More importantly perhaps, this would also leave more time for discussion of the applications by interested members of the Study Section. I would still need the written copy for the purpose of preparing the Summary Statements but I believe the consensus of the group felt that the level of interest for each application would be considerably improved, resulting in a better review of each application with interaction of more members of the Study Section, if these suggestions are followed. Let's try to implement this slight change in our review procedure, and still be consistent with your own style of grant review, at the upcoming meeting.

A final point I would like to make in this regard is that, as many of you surely know, institutional administrators often use the Summary Statements to make tenure and promotional decisions. Although your written (and verbal) comments should accurately reflect your appraisal of the proposed research, the best interests of the investigators should also be kept in mind. Remember critique implies both positive and negative evaluations.

Continued

August 22, 1986

FIGURE 47 (cont)

A single sheet form is enclosed for each application to serve as the first page of your written comments. If more forms are needed, please let us know. After typing your comments (DOUBLE SPACE), please have your secretary assemble three copies, collated and stapled; the original may serve as your copy. Please give Mrs. Nancy Pursell two copies of each review as soon as you arrive. Because of the problems we generally experience with the mail, I recommend not mailing copies of your reviews ahead of time unless it is more convenient to you.

Additional Information: If any of the applications assigned to you presents a problem which might be resolved by securing additional information, especially if it can be obtained from the principal investigator, please let me know so that we may attempt to gather the information necessary to facilitate your review.

I have also enclosed a previously prepared Suggestions information sheet which duplicates some points raised above and addresses other items which are of use in completing the review process.

Additional information, applications and notification of any changes will accompany a later mailing. May I again remind you that if you receive any application you do not wish to review either because of a misassignment or for personal reasons, it would be appreciated if you would call this office as soon as possible so that an alternate assignment for preliminary review can be made as rapidly as possible.

Please bring all applications and assignments to the study section meeting.

Should you have any questions, please do not hesitate to call us at 301-496-7305.

I am looking forward very much to seeing and working with each of you in October.


John L. Meyer, Ph.D.

Enclosures

AGENDA 8605 PTHA

SAMPLE

AGENDA
 PATHOLOGY A STUDY SECTION
 FEBRUARY 19-21, 1986
 RAMADA BETHESDA
 8400 Wisconsin Avenue
 Bethesda, Maryland 20814
 (301) 654-1000

WEDNESDAY, FEBRUARY 19, 1986

| | | |
|-----------------------|---|------------|
| 8:00 a.m. | Call to Order | Dr. Pietra |
| 8:00 a.m. - 8:45 a.m. | Administrative Remarks (Open to the public) | Dr. Meyer |
| 8:45 a.m. | Consideration of Grant Applications (Closed) | Dr. Pietra |
| 8:45 a.m. - 1:00 p.m. | AM category (17 applications) | |
| 1:00 p.m. - 2:00 p.m. | LUNCH | |
| 2:00 p.m. - 2:45 p.m. | AM (continued) | |
| 2:45 p.m. - 6:00 p.m. | HL Category (60 applications) | |

THURSDAY, FEBRUARY 20, 1986

| | |
|-----------------------|----------------|
| 8:00 a.m. - 1:00 p.m. | HL (continued) |
| 1:00 p.m. - 2:00 p.m. | LUNCH |
| 2:00 p.m. - 6:00 p.m. | HL (continued) |

FRIDAY, FEBRUARY 21, 1986

| | | |
|-------------------------|------------------------------|------------------------|
| 8:00 a.m. - 12:00 p.m. | HL (continued) | |
| 12:00 p.m. - 12:15 p.m. | AG Category (1 application) | |
| 12:15 p.m. - 12:45 p.m. | AI Category (2 applications) | |
| 12:45 p.m. - 1:45 p.m. | LUNCH | |
| 1:45 p.m. - 3:30 p.m. | CA Category (6 applications) | |
| 3:30 p.m. - 3:50 p.m. | HD Category (1 application) | |
| 3:50 p.m. - 5:30 p.m. | NS Category (6 applications) | |
| 5:30 p.m. - 6:00 p.m. | Final Remarks | Drs. Meyer & Pietra |
| 6:00 p.m. | Adjournment | Dr. Pietra |

* Times approximate Institute representatives should judge accordingly.

PATHOLOGY A STUDY SECTION

June 10-13, 1986

ROSTER

CHAIRPERSON

PIETRA, Giuseppe G., M.D.
Professor of Pathology & Director
Division of Anatomic Pathology
Hospital of the University of
Pennsylvania
Philadelphia, Pennsylvania 19104

BAENZIGER, Nancy L., Ph.D. *
Research Associate Professor
Dept. of Anatomy & Neurobiology
Washington University
School of Medicine
St. Louis, Missouri 63310

BLANTZ, Roland C., M.D.
Professor of Medicine
Chief, Nephrology Section
Veterans Administration Med. Ctr.
San Diego, California 92161

COUSER, William G., M.D.
Professor of Medicine
Head, Division of Nephrology
University of Washington
School of Medicine
Seattle, Washington 98195

CRAPO, James D., M.D.
Professor of Medicine
Department of Medicine
Duke University Medical Center
Durham, North Carolina 27710

FOWLER, Stanley, Ph.D.
Professor of Pathology
Department of Pathology
University of South Carolina
Columbia, South Carolina 29208

FREEMAN, Bruce, Ph.D. *
Associate Professor
Department of Anesthesiology
University of Alabama
Birmingham, Alabama 35294

GAMBETTI, Pierluigi, M.D.
Professor of Neuropathology
Director, Div. of Neuropathology
Case Western Reserve University
School of Medicine
Cleveland, Ohio 44106

GIMBRONE, Michael A., Jr., M.D.
Professor of Pathology
Department of Pathology
Brigham and Women's Hospital
Boston, Massachusetts 02115

HUDSON, Billy G., Ph.D.
Professor of Biochemistry
Department of Biochemistry
University of Kansas Medical Center
Kansas City, Kansas 66103

JOHNSON, Alice R., Ph.D.
Research Professor
Department of Biochemistry
The University of Texas Health Ctr.
Tyler, Texas 75710

KANWAR, Yashpal S., M.D., Ph.D.
Professor of Pathology
Department of Pathology
Northwestern University
Medical School
Chicago, Illinois 60611

KIRKPATRICK, Joel B., M.D. *
Professor of Pathology
Baylor College of Medicine
Houston, Texas 77030

LEWIS, Edmund J., M.D.
Professor of Medicine
Department of Medicine
Rush-Presbyterian-
St. Luke's Medical Center
Chicago, Illinois 60612

PATHOLOGY A STUDY SECTION
June 10-13, 1986
ROSTER

PHAN, Sem H., M.D.
Assistant Professor of Pathology
Department of Pathology
Univ. of Michigan Medical School
Ann Arbor, Michigan 48109

PLOPPER, Charles G., Ph.D. *
Chairman and Associate Professor
Department of Anatomy
School of Veterinary Medicine
University of California
Davis, California 95616

RILEY, David J., M.D.
Associate Professor
Department of Medicine
CMDNJ-Rutgers Medical School
New Brunswick, New Jersey 08903

SHASBY, Douglas Michael, M.D. *
Assistant Professor
University of Iowa
College of Medicine
Iowa City, Iowa 52242

TOWNSEND, Jeannette J., M.D.
Associate Professor of
Pathology and Neurology
Department of Pathology
University of Utah
School of Medicine
Salt Lake City, Utah 84132

ULEVITCH, Richard, Ph.D. *
Associate Member
Department of Immunology
Research Inst. of Scripps Clinic
La Jolla, California 92037

WEBSTER, Robert O., Ph.D. *
Associate Professor
Department of Internal Medicine
St. Louis University
School of Medicine
St. Louis, Missouri 63104

EXECUTIVE SECRETARY
MEYER, John L., Ph.D.
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20892

GRANTS TECHNICAL ASSISTANT (Optional)
PURSELL, Nancy L.
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20892

* Special Reviewers

Consultants are required to absent themselves from the
any application if their presence would constitute a
a conflict of interest.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Study Section
 Westwood Building, Room _____

Subject: Supplies for Study Section Mailing/Meeting

Office Services Section
 Westwood Building, Room 438

Please deliver the following items to our Study Section for our members for mailing/meeting of the Study Section. The date of the meeting is _____.*

_____ #7 Jiffy Bags
 _____ #6 Jiffy Bags
 _____ Small Boxes
 _____ Large Boxes
 _____ Letter Size Accordion Folders

Date Received: _____

* NOTE: Requests must be submitted to Office Services Section at least two weeks before anticipated mailing.

PLEASE COMPLETE FOR OFFICE SERVICES SECTION INVENTORY PURPOSES:

NAME OF STUDY SECTION: _____
 Westwood Building, Room _____
 Meeting Date: _____

_____ #7 Jiffy Bags
 _____ #6 Jiffy Bags
 _____ Small Boxes
 _____ Large Boxes
 _____ Letter Size Accordion Folders

Date Delivered: _____

SEE MOST RECENT VERSION.

ENTER NUMBER OF DUPLICATE SETS (0 - 5)

0

DO YOU WANT THE ADMINISTRATIVE DATA LIST?

Y

DO YOU WANT THE WORKSHEETS?

Y

nnn IS YOUR JOB NUMBER

AMPLE SCORING SHEET

SCORING SHEET FOR: TM' APPLICATION NO. *VOTE

GROUP: 02 CYCLE: 01-85 VOTER: 01 PAGE 1 RUN DATE: 09. FELLOWSHIP

1. 1 F32 AI 07264-01 MAYNARD, EDWARD C U S NATIONAL INSTITUTES OF HEALTH 4 YRS
 2. 1 F32 AI/GM 07266-01 FISHER, GREGORY M CARNEGIE-MELLON UNIVERSITY 4 YRS
 3. 2 R22 AI 11289-13 COLLEY, DANIEL G VANDERBILT UNIVERSITY
 4. 2 R22 AI 11847-18 BARR, CLARKE R UNIVERSITY OF CALIFORNIA LOS ANGELES

13. _____
 14. _____

If approval, insert score, otherwise use letters: DS=disapproval DF=deferral AB=abstention CF=conflict NP=not present

If item 391 (dual program class code) contains data, it will print behind item 091 (program class code).

SEE MOST RECENT VERSION.

PAGE 1

ADMINISTRATIVE DATA LIST

IS REPORT NO. 5

09/21/84

APPLICATION NUMBER: 1 R22 AI22237-01

VIEW GROUP: TMP

GROUP: 02

DUAL: GM

ETING DATE: OCT./NOV. 84

40 P

VESTIGATOR: BOROS, DOV L

DEGREE: PHD

GANIZATION: WAYNE STATE UNIVERSITY

TY, STATE: DETROIT, MICH

REQ. START DATE: 04/01/85

OBJECT TITLE: CLONING OF S. MANSONI EGG ANTIGENS IN BACTERIA, YEAST

ECIAL NOTE: 20-HS. INV.-NO EXEMPTION DESIGNATED
99-ANIMAL USE CODE INVALID-CORRECTION REQUIREDPROJECT
YEARDIRECT COSTS
REQUESTED

178

01
02
0395,595
100,272
115,098

RECOMMENDED BUDGET

| BUDGET CATEGORIES | 01 YEAR | 02 YEAR | 03 YEAR | 04 YEAR | 05 YEAR | 06 YEAR | 07 YEAR |
|-------------------|---------|---------|---------|---------|---------|---------|---------|
| PERSONNEL | | | | | | | |
| CONSULTANT COSTS | | | | | | | |
| EQUIPMENT | | | | | | | |
| APPLIES | | | | | | | |

etc.

| | | | | | | | |
|--------------------|--|--|--|--|--|--|--|
| OTHER EXPENSES | | | | | | | |
| TOTAL DIRECT COSTS | | | | | | | |

APPROVED WITH REDUCTION _____ APPROVED AS REQUESTED _____ DIS _____ DEF _____

(VOTE SHEETS continued on next page)

SAMPLE WORKSHEET

If item 391 (dual program class code) contains data, it will print behind item 091 (program class code).

INITIAL REVIEW GROUP WORKSHEET

AS OF 09/21.
COUNCIL DATE: JANUARY 1985
MEETING DATE: OCT./NOV. 1984

REVIEW GROUP: TROPICAL MEDICINE & PARASITOLOGY SS

RECOMMENDATION
APPROVAL RATING OTHER

APPLICATION, APPLICANT & ORGANIZATION

SUPPORT REQUESTED

4 YRS 7 MOS

1 F32 AI07266-01 DUAL: GM SPONSOR: TAYLOR, D L
FISHER, GREGORY W 30 B
CARNEGIE-MELLON UNIVERSITY
PITTSBURGH, PA
VISUALIZATION OF FMLP-RECEPTORS DURING CHEMOTAXIS
10-NO HUMAN SUBJECTS INVOLVED
98-NOT SUBJECT TO ANIMAL CODING SYSTEM

2 R22 AI11289-13 YEAR 13 114,191
COLLEY, DANIEL G 14 102,479
VANDERBILT UNIVERSITY 15 111,617
NASHVILLE TENNESSEE 16 121,607
IMMUNOLOGIC RESPONSES TO SCHISTOSOMA MANSONI 17 132,499
20-HS INV.-NO EXEMPTION DESIGNATED
-ANIMAL USE CODE IS MISSING/INVALID

179

2 R22 AI11847-18 YEAR 18 115,386
BARR, CLARKE R 19 127,062
UNIVERSITY OF CALIFORNIA LOS ANGELES 20 139,371
LOS ANGELES CALIFORNIA
BIOLOGICAL CONTROL OF FILARIASIS VECTORS
20-HS INV.-NO EXEMPTION DESIGNATED
10-NO LIVE VERTEBRATE ANIMALS INVOLVED

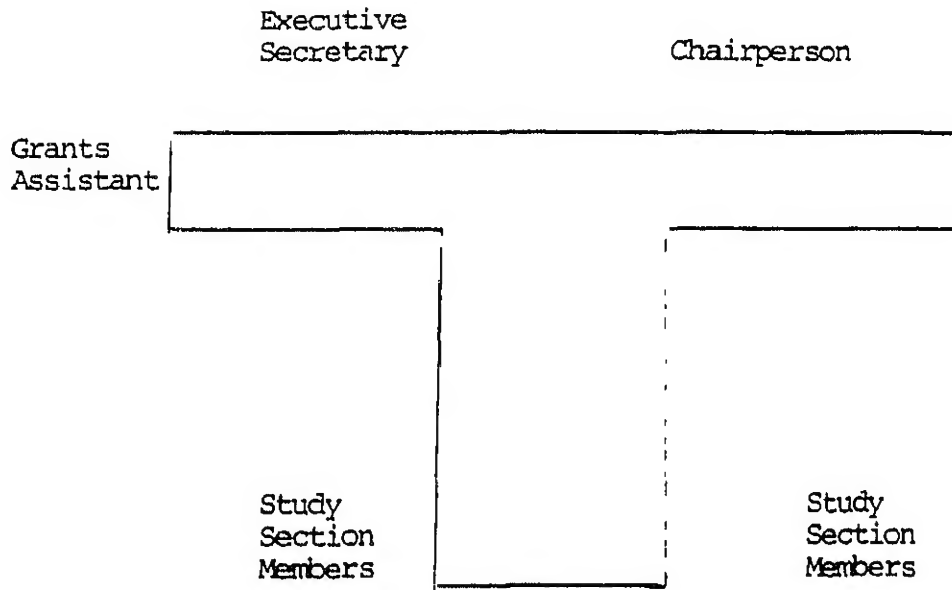
1 R22 AI22077-01 YEAR 01 146,311
CLARKE, ARTHUR H
ECORESEARCH, INC
MATTAPOISETT, MA
SURVEY OF SCHISTOSOMA MANSONI VECTORS IN CENTRAL AMERICA
20-HS INV.-NO EXEMPTION DESIGNATED
10-NO LIVE VERTEBRATE ANIMALS INVOLVED

1 R22 AI22092-01 DUAL: EY
LANGHAM, MAURICE E
JOHNS HOPKINS UNIVERSITY
BALTIMORE, MD
PHARMACOLOGIC STUDIES ON ONCHOCERCIASIS
10-NO HUMAN SUBJECTS INVOLVED
99-ANIMAL USE CODE INVALID-CORRECTION REQUIRED

ASSIGNMENT LIST BY APPLICATION I.D. NUMBER

| COUNCIL DATE: 0188 | STUDY SECTION: RNM | FLEX: ALL | REVIEW: | GROUP CODE: ALL |
|--------------------|--------------------|-----------|----------------------|-----------------|
| GRANT NUMBER | IRG/FLEX/AHR/GC | P.I. | P.I. | REVIEWERS |
| 1R01 HL 40567-01 | RNM | | PICKERING, THOMAS G | |
| 1R01 HL 40598-01 | RNM | | ALMOND, CARL H | |
| 1R01 HL 40604-01 | RNM | | REICHEK, NATHANIEL | |
| 1R01 NS 24710-01A1 | RNM | | HARNISH, PHILLIP | |
| 1R01 NS 25893-01 | RNM | | HAUGHTON, VICTOR M | |
| 1R01 NS 25921-01 | RNM | | HACKNEY, DAVID | |
| 1R15 NS 25979-01 | RNM | | HORNAK, JOSEPH P | |
| 1R01 NSHL 26066-01 | RNM | | DILMANIAN, F AVRAHAM | |
| 1R01 NS 26164-01 | RNM | | HANSON, ROBERT N | |

SAMPLE SEATING ARRANGEMENT DURING MEETINGS



t in TRIPLICATE Please read carefully, including information on reverse

Reviewer's Name

Department of Health and Human Services
Public Health Service, National Institutes of Health

DATE

Claim for Reimbursement of Travel Cost, Per Diem, and Consultant Fee

OF CHAIRMAN

STUDY SECTION, REVIEW GROUP, OR COMMITTEE

S AND DATES OF ASSIGNMENT

Note. In cases of combined personal and official business during the same trip, show departure and return time that could have been followed for the sole purpose of this assignment. Take this into account in itemizing expenses below.

City, date, hour)

DATE OF MEETING(S) OR SITE VISIT(S)

INED (City, date, hour)

st of transportation (receipts required). If mixed mode of travel, indirect routing or stopovers for personal sons are involved, claim only cost of usual direct-route round-trip fare. If travel is by privately owned ne, 45¢ an air mile is allowed; or by private auto, _____ ¢ a mile (not to exceed cost by common rier) will be allowed.

ometer Readings:

Amount of Advance (when applicable): \$

\$

d) or limousine used for official business, including up to 15% for tips (Receipt not required.)

\$

ter (Examples - Road and bridge tolls, parking, telegram and telephone calls for official business, ference room rentals) Receipts required only on items costing \$25 or more. Flight or other travel urance is considered a personal expense and is not reimbursable

ntify claims:

\$

TAL TRAVEL EXPENSES

gling: Itemize each day's lodging costs (including tax). This information is ded to determine the appropriate per diem allowance under the Standard nus system, and the Per Diem Locality Rate method. (See reverse.)

REMARKS: If unusual circumstances regarding an assignment affect your claim, explain here or on an attached page.

| DATE | LODGING | MEALS AND INCIDENTAL EXPENSES | TOTAL |
|------|---------|-------------------------------|-------|
| | \$ | \$ | \$ |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

I certify that the above itemization reflects costs incurred for official business and that I provided consultant services in connection with this assignment on the dates indicated.

ADDRESS

ADDRESS (where check is to be mailed if other than home)

L SECURITY NO.
Privacy Act statement on reverse)

NAME (typed)

SIGNATURE OF CONSULTANT

I certify that the above Consultant is entitled to a consultant fee for _____ days at \$100 per day.

\$

Signature of Executive Secretary:

Standard Conus \$ /Per Diem Locality Rate \$

\$

Travel (from Item D, above)

\$

ADVANCE DEDUCTED (when applicable)

TOTAL TO BE PAID

\$

illed by

Approved by

☒ Code

VOUCHER NUMBER PREFIX CODE

- A - Regular Member Meeting
- B - Regular Member Site Visit
- D - Ad Hoc Consultant Meeting
- E - Ad Hoc Consultant Site Visit

* Regular Member means DRG study section member for this project.

CHRONOLOGICAL RECORD OF CLAIMS FOR
TRAVEL REIMBURSEMENT
FOR CONSULTANTS
AND ATTENDANCE RECORD

SECTION:
SECTION MEETING DATE:

[illegible]

FIGURE 59

INSTRUCTIONS:

SHIPPING OFFICER . - After carrier has completed pick-up of the shipment, attach original to a copy of the Government Bill of Lading to back up authorization for shipment, and return the other completed copy of this form to the requesting office.

| | | |
|-------------|----|---------------------------|
| SHIPMENT OF | == | GOVERNMENT OWNED PROPERTY |
| | == | OTHER |
| | — | (Identify) |

| | |
|---|------------------------------|
| 2. NAME OF REQUESTING BUREAU, DIVISION, STATION, OFFICE OR EMPLOYEE (Consignor) | 3. TELEPHONE NO. & EXTENSION |
|---|------------------------------|

4 ADDRESS (Building Name, Number, Street, City, Zone, State or Country)

5. LOCATION OF PROPERTY TO BE SHIPPED (Building, Room No., Street, City, Zone, State or Country.)

4. SHIPMENT TO BE BY

GOV'T BILL OF LADING

☐ CONVERSION TO GBL

— COLLECT

7. DESCRIPTION OF ARTICLES
(Including Stock or Property No.)

When property of varying descriptions is to be shipped, segregate by line item quantity and value of each line item:

| B. | Quantity |
|----|----------|
|----|----------|

Value

(If additional space needed, use reverse side)

TOTAL

10. ☐ PACK ☐ CRATE ☐ SPECIAL PACKING (Explain)

SHIP TO (CONSIGNEE) Name, Street, City, Zone, State or Country

12. ADDITIONAL INFORMATION INSTRUCTIONS OR JUSTIFIC
EXPEDITED MODE OF SHIPMENT

13. DATE SHIPMENT MUST ARRIVE AT DESTINATION

14. PROPERTY CLEARANCE (Signature of Property Accountable
or Other Officer)

15. COMMON ACCOUNT NO.

16. SIGNATURE OF ADMINISTRATIVE OFFICER OR DESIGNEE

DATE

This information may be used by the shipping office/requesting office in keeping data on shipments.

MODE OF TRANSPORTATION

DATE SHIPPED

| | |
|------------|--|
| 8/L NUMBER | |
|------------|--|

NO OF PIECES

TOTAL WEIGHT

Chapter VIII

ROLE OF THE GRANTS ASSISTANT DURING STUDY SECTION MEETINGS

A. SETTING UP OF THE MEETING ROOM

Whenever possible, the conference room should be set up the night before the meeting. Otherwise, the Grants Assistant should arrange to have it ready about an hour before the meeting starts.

For meetings held off of the NIH campus or out-of-town, the Grants Assistant should inspect the meeting room as soon as possible. Inadequate lighting, insufficient number of chairs, heating or cooling problems, no table for extra materials, or inadequate conference tables may be encountered, and these problems may take some time to resolve with the hotel personnel.

Each "place setting" should include:

- Member's meeting folder,
- Paper from large ruled tablet,
- Pencils or pens, and
- Other meeting materials.

Name plates are optional and are omitted for out-of-town meetings. However, when name plates are not used, a seating chart should be posted on the door next to the agenda. The Grants Assistant should make arrangements with the hotel to provide ice water and glasses. A phone in the room is optional. Smoking is not permitted at Government conferences.

At a side table close to the door, there should be a log book or sign-in sheet for all individuals attending the meeting to sign. Multiple copies of the agenda, roster, listing of applications, and seating chart should also be displayed at this location. Two sets of summary statement books from the previous meeting should be available for examination by the study section members.

I. RESPONSIBILITIES DURING THE MEETING

The Grants Assistant is the "right arm" of the Executive Secretary and Chairperson during the meeting, and should be seated at the head table next to the Executive Secretary. The Grants Assistant takes whatever notes are considered necessary during discussion and actions. This does not involve verbatim note-taking of members' reviews, since written copies are turned in before or during the meeting; however, all votes, motions, and budget changes should be recorded. The Grants Assistant should also be alert to the need for study section members to leave the room during discussion of applications from their own organizations, and should assume the responsibility for telling the members when to return to the room. (A more

detailed explanation of where other conflicts exist can be found in Chapter XV, Section A.)

The Grants Assistant should be knowledgeable about quorum rules. A quorum exists when one more than half of the chartered members are present. (For example, if there are 18 chartered members, a quorum exists when there are 10 or more chartered members present.)

The Grants Assistant is also responsible for ensuring that all members sign the Certification of No Conflict of Interest (see Chapter XI) before leaving the meeting. During the meeting, the Grants Assistant is responsible for collecting the reviewers' comments. At the close of the meeting, the Grants Assistant should make sure that she or he has received all reviewers' comments and has collected the scoring sheets.

At all times during the meeting, the Grants Assistant should be alert to the need for security precautions, so that confidential material is not allowed out of the room and unofficial visitors are not admitted. Appropriate visitors should list their names, titles, and organization on the sign-in sheet and should be identified to the group either by the Executive Secretary or the Chairperson. If the meeting lasts more than 1 day, the conference room must be adequately secured overnight.

DISPOSITION OF WASTE MATERIAL FOLLOWING MEETINGS

Disposition of confidential material, whether on or off the reservation, requires the personal attention of the Grants Assistant. All material should be removed from tables, chairs, and floor, with trash disposed of and material to be saved returned to the office.

1. NIH Meetings

Material of a classified or confidential nature must not be placed in wastebaskets. Included are such items as applications, summary statements, workbooks, reviewers' comments, assignment sheets and project site visit reports.

Extra cardboard cartons and/or large plastic trash bags are used for disposing of trash. These containers should be sealed or closed securely and marked TRASH or DESTROY. Containers so marked will be destroyed by the NIH.

2. Off-Reservation Meetings

- a. Washington D.C. Metropolitan Area. The confidentiality of material must be protected at all meetings; circumstances and common sense will dictate the necessary protective measures. For example, when the meeting has been held in the Washington D.C. metropolitan area, the trash material may be returned to the NIH for disposition, destroyed at the hotel or motel, or torn or shredded (so that it cannot be pieced together) before being disposed of by hotel staff. If the material can be disposed of at the hotel, arrange for hotel

staff to remove it immediately. Confidential material should not be left in hallways.

Either cardboard cartons or clear plastic bags can be used for disposing trash. The bags or cartons should be sealed or closed tightly and marked TRASH or DESTROY.

- b. Out-of-Town. It is usually impracticable to return waste material to the NIH from an out-of-town meeting. One should use the previously described precautions.

D. TRANSPORTATION OF ESSENTIAL REVIEW MATERIALS BACK TO THE STUDY SECTION OFFICE

BEWARE!! Boxes marked TRASH in 6-inch high letters may not always be distinguished by hotel staff from similar boxes not so marked, but carrying NIH return address labels or tags. Therefore, at the conclusion of a study section meeting, the Executive Secretary and Grants Assistant should ensure that at least the following items are hand-carried back to the office, rather than packed in boxes for transportation:

- Scoring Sheets,
- Reviewers' comments and outside opinions,
- Amended budgets, and
- Notes taken at the meeting.

If at all feasible, everything except trash should be hand-carried back from a meeting. If not, be sure that any boxes for transportation are left in a different room from boxes of trash. The opposite side of the same room is not good enough. If there is a baggage room, boxes for transportation should be checked into this room before the study section staff leave the hotel.

If available, use tub files rather than boxes for all papers to be transported back to NIH.

All cartons or containers handled by the NIH Transportation Unit should be packed and covered or sealed in such a manner as to prevent papers from being blown and scattered during transportation. They should be clearly marked to identify the study section's NIH mailing address and telephone number.

Chapter IX

POST-MEETING FOLLOW-UP

A. ATTENDANCE RECORD

The Grants Assistant prepares an attendance record, to be used only within the study section office, indicating the number of days each member attended the meeting. Attendance for part of a day is counted as a full day. If a member made a project site visit en route to the meeting, or if the Chairperson issued advance payments (only in the amount of coach airfare) to some of the study section members at the meeting, this information should be included on the attendance record. The attendance record (Figure 60) is then used as a check when consultant travel vouchers arrive in the office. Such travel vouchers are to be recorded as received, signed by the Executive Secretary, and forwarded immediately to DRG Travel. Do not hold the vouchers for batch transmittal. When the vouchers are returned by Travel, they are to be recorded as received and mailed immediately to the study section Chairperson for payment.

B. SUMMARY OF DATA SHEETS

The Grants Assistant completes the Summary of Data (Figure 61), which is sent to each study section by the Office of the Deputy Chief for Review. The completed form is returned to that office immediately.

C. CALCULATION OF PRIORITY SCORES

Specific information on voting procedures can be found in "Review Procedures for Initial Review Group (IRG) Meetings," a leaflet that is given to all study section members. (See Chapter VII.) The Grants Assistant should understand these procedures thoroughly.

In the case of an approval with a split vote, all members should record a rating. If a reviewer who opposed the motion for approval does not enter a score, the vote should be entered as AB (abstention). AB does not count in calculating the priority score.

The individual member scoring sheets for each meeting should be destroyed as soon as possible after verification. Under no circumstances should the individual votes of members be divulged to anyone.

All priority scores are to be calculated by the Grants Assistants using the modem-equipped IBM Displaywriter. This priority score system allows the Grants Assistant to display the information and order, in printed form, the totals, the score matrices of individual voters, a list of scores for each application, and a voter verification list.

If an unusual circumstance arises, such as a PL-480 application, where a Grants Assistant has to compute priority scores by hand, scores voted by members must be added and the total multiplied by 100. This figure is then divided by the number of members voting on the particular application.

PREPARATION OF BUDGET ADJUSTMENTS

Although the preparation of budget adjustments for applications recommended for approval is the responsibility of the Executive Secretary, this responsibility is often shared with the Grants Assistant. Therefore, the Grants Assistant should be familiar with the procedure. For example, a recommended personnel budget is obtained by deducting the total salary and fringe benefits, eliminated or modified by the study section, from the total personnel budget requested. If similar personnel budget deletions are recommended for future years, the same sum used for the first year should be deducted from personnel costs in subsequent years. A similar procedure should be used when calculating figures for "Supplies," "Other Expenses," etc. unless the study section has made a specific recommendation (for example, "Supplies should be held to \$8,000 per year.").

PROCEDURE FOR OBTAINING SUMMARY STATEMENT TOPS AND RESUMES OF RECOMMENDATIONS

Using the modem-equipped IBM Displaywriter, Grants Assistants can directly correct the information that will appear on the summary statement tops and obtain the resume of recommendations. The procedure is explained in detail in the computer instruction printouts available from the User Resource Office (Room 225). (Printouts may be ordered by using Function Number 8 in the DRG computer system and ordering documentation for the IRG Interface System.) The Grants Assistant should:

(1) Change the Human Subjects Codes. This includes, first, changing any incorrect Code 10 (no human subjects) to Code 20 (human subjects) and then, using the sweep human subjects command, changing all code 20's to 30's. Any human subjects code that needs further modification (i.e. 30 to 44, 45, 47 or 49) must be changed individually;

(2) Similarly change or correct Animal Codes as necessary;

(3) For each application, insert recommended budgets and any other necessary changes. These changes could include shortening of application titles, correcting spelling of investigator's name, correcting investigator's degree, etc;

(4) Request "Report 5; Administrative Data List" (see Chapter VII) and check that all information is correct. If not, make the changes and request another Administrative Data List. All information should appear in correct form on the Administrative Data List before releasing it to the main computer files;

(5) Release the data. The computer system will then automatically correct IMPAC and issue the Resume of Recommendations; and

(6) If it is necessary to make corrections on summary statement tops at a later date (before laser printing), make the necessary changes, using the modem-equipped IBM Displaywriter. Again, request "Report 5; Administrative Data List" and check that the new information has been accepted by the computer system. Each time new information is added, check the Administrative Data List before releasing it again.

F. FINAL ACCURACY CHECK

The Administrative Data List, obtained from the computer system, must be checked for accuracy by the Grants Assistant. This list will contain all information as it will appear on both the Resume of Recommendations and the summary statement tops. The accuracy check should include the following items.

- Budgets, priority scores, and recommendations;
- Human subject and animal codes; and
- Recommendations of the study section. One of the following should be indicated for each application: approval, disapproval, deferral.

G. RELEASE

Within two working days after study section meetings, the Grants Assistants should enter into their workfile, IRG actions, priority ratings to calculate priority scores, human subject codes, and animal subject codes and then release these data to IMPAC. The first release will automatically transfer into IMPAC "Funds Requested" to "Funds Recommended." Then the Grants Assistant will enter any modifications to the requested budgets and release a second time, which will modify those budgets with the recommended changes. Any changes made in human codes, animal codes, budgets, etc. must be accompanied by a release in order to get the corrections into IMPAC.

H. RESUME OF RECOMMENDATIONS, PRINTING AND DISTRIBUTION

When all corrections and changes have been made (after summary statements have been typed), final copies of the Resume of Recommendations may be obtained from the computer and distributed in accordance with the Distribution Guide. The Grants Assistant may have the necessary copies made either at the DRG Duplicating Room or at the Print Shop. It is no longer necessary to send copies of the resume to the Institutes, for the information is available to them from the computer.

ATTENDANCE SHEET

195

FIGURE 61
SUMMARY OF DATA
STUDY SECTION REVIEW CYCLE

_____) Review Cycle (_____) Council
Month/Year Month/Year

SS Code _____

Use complete and return to
Irving Simos, Rm. 338 (WB)
A.P.

Study Section/Review Group

Executive Secretary

COMMITTEE REVIEW OF R, F, K, P, M, S, T APPLICATIONS (Do not include SBIR & AREA
Applications)

No. of Applications _____

No. of Site Visits _____

No. of Outside Opinions Obtained _____

No. of Ad Hoc Reviewers: Govt. _____ Other _____ (

SBIR APPLICATIONS

No. of Applications _____

No. of Site Visits _____

No. of Outside Opinions Obtained _____

No. of Ad Hoc Reviewers: Govt. _____ Other _____

AREA APPLICATIONS

No. of Applications _____

No. of Site Visits _____

No. of Outside Opinions Obtained _____

No. of Ad Hoc Reviewers: Govt. _____ Other _____

Completed by _____
Date Submitted _____
/RRB

Chapter X

PREPARATION AND DISTRIBUTION OF SUMMARY STATEMENTS

A. GENERAL INFORMATION

Summary statements are prepared by the Executive Secretary from reviewers' written comments and notes taken of the discussion that ensued at the study section meeting. The Grants Assistant should review the information that will appear on summary statement tops for accuracy and make necessary corrections before typing the summary statements. It will be necessary to release the data again to correct the IMPAC File. (See Chapter IX, Section G.)

When the copies are received from the laser printer, they should be checked by the Grants Assistant. A copy should then be sent to the appropriate Lead Grants Technical Assistant and also to the appropriate Institute(s).

A Summary Status Report (Figure 62) should be submitted to the appropriate Lead Grants Assistant by the close of business every Friday (beginning the first full week after the study section meeting) regardless of the progress. This allows the Section Chief to keep an accurate assessment of the workload flow of the entire office.

All summary statements should be written and typed within 25 working days after the meeting. If for some reason this deadline cannot be met, the problem should be discussed with one's Section Chief, RRB.

Those Councils meeting first should receive their summary statements first. The current Schedule of Council Meetings will guide the Executive Secretary and Grants Assistant in the proper order for sending summary statements to the Institutes.

B. GENERAL GUIDELINES

Although the Executive Secretary is responsible for developing summary statements, the Grants Assistant can help by keeping the following guidelines in mind as the statements are being typed:

1. Each summary statement should be complete in itself, because all readers may not have access to the application, background information, or previous summary statement.
2. Percentiles are now figured automatically as soon as the Grants Assistant releases the data to the IMPAC system. However, it is important to check that the figures are in place for those Institutes that use percentiles when the summary statements have been printed by the laser printer.
3. Even when the same comments apply to two or more applications, summary statements must be prepared for each application.

4. The evaluation should reflect the study section recommendation, priority score, and recommended budget and duration of support. Reasons for changes, such as a recommended reduction in the requested budget or period of support, should be adequately explained.
5. A summary statement on a supplemental application should include a brief description of the basic project as well as information about the supplemental request. Be sure the previously recommended column is completed with the appropriate amounts.
6. Criticisms must be directed at the application not the investigator. References to the age, race, sex, or country of birth of an investigator are not significant to the application and must not be included; negative personal comments should be avoided, if possible, or cast in a polite and civil manner if necessary to substantiate the recommendation.
7. Summary statements should not indicate that the study section had difficulty making a recommendation because of a lack of information; this implies lack of preparation on the part of the staff. While questions arise during meetings that can not be anticipated, adequate information should be available on such items as methodology, research design, need for equipment and training, and experience of personnel. If insufficient information was available, the application should have been deferred.
8. Do not repeat information printed at the top of the summary statements.
9. Names of reviewers or referees (RCDAs, fellowships) are never written in the summary statement, and first person pronouns (I, me, my) should not be used. The review is a collective process.
10. Abbreviations should be used sparingly. Type the official names of universities, foundations, NIH Institutes, Government agencies, councils, and study sections. Scientific terminology should be spelled out initially with the abbreviation in parentheses. The abbreviations may then be used in the balance of the summary statement.
11. When the principal investigator is referred to in the summary statement, do not use the initials "P.I." Also, the person's title and name should be kept together, e.g., "Dr." should not appear at the end of one line and "Jones" at the beginning of the next.
12. Excessively long paragraphs should be avoided.
13. Construction and punctuation should be uniform for any series of phrases or clauses.

Two books that can help Grants Assistants are Word Division and Reference Manual for Stenographers and Typists. Both books are available in the Self-Service Store.

2. TYPING FORMAT

Instructions available in the User Resource Office entitled "Procedures for Creating On-Line Summary Statement File" must be followed in formatting summary statements.

3. SPECIAL NOTES

The purpose of the special note is to alert Institute staff to problems that need special attention. The note is typed in capital letters, underlined, and placed on the line immediately below the identifying number on the first page of the summary statement. Examples of such notes follow:

• FOREIGN

For applications from a foreign country, the project must present special opportunities for furthering research programs. These would be through the use of special talents, resources, populations or environmental conditions in other countries which are not readily available in the United States or which provide augmentation of existing United States resources. The summary statement will have a special paragraph (CRITERIA FOR FOREIGN AWARD), which covers these criteria. This special paragraph includes such issues as human subjects, animals welfare, unusual diseases, equipment, techniques, whether similar research is being done in the United States, and whether there is a need for additional research in this area.

• SPLIT VOTE: FOR THE MOTION; AGAINST THE MOTION; ABSTAINING FROM THE MOTION; ASSIGNING A SCORE.

The specific recommendations of the study section should be recorded as above.

• ADMINISTRATIVE NOTE

This is used to clarify a situation that was not directly discussed or resolved by the study section or was related to aspects other than merit. Included are concerns about policy or other issues considered important enough to be brought to the attention of the Institute or Council, i.e., budgetary overlap with other grants. A special section, entitled ADMINISTRATIVE NOTE, is added at the end of the summary statement.

• PREVIOUSLY DEFERRED

This comment should be followed by FOR PROJECT SITE VISIT or FOR ADDITIONAL INFORMATION, or FOR REREVIEW.

• OUTSIDE OPINION(S) OBTAINED

When an outside opinion was used, this phrase is typed in.

• BIOHAZARD

The potential biohazards are explained in a separate paragraph at the end of the critique headed, BIOHAZARD. A more detailed explanation of potential biohazards is found in Chapter XV, Section G.

• REVISED (Followed by date) SEE NOTE

At the end of the summary statement there should be a paragraph entitled, REVISION NOTE, in which a short explanation or indication for the revision is given.

E. INSTRUCTIONS FOR SUMMARY STATEMENT TEXT

When preparing a summary statement, the Executive Secretary and Grants Assistant should use the titles listed below. Every research summary statement should include at least a RESUME, DESCRIPTION, and CRITIQUE. These sections may be sufficient for disapproved applications, but other sections will be needed for approved applications. Complete sentences should be used throughout; the budget, for example, should not be described as simply "Reasonable" or "Adequate." Do not use jargon, vernacular expressions, and undefined abbreviations in reporting the scientific review. Colloquial language used in the reviewers' comments should be presented in a literary style acceptable for scientific reports.

- RESUME: Briefly summarize the proposed project and the essential reasons for the recommendation. Split votes are mentioned in this section and again in special sections as CRITIQUE (MAJORITY) AND CRITIQUE (MINORITY). Any special notes are also addressed briefly.
- DESCRIPTION (Adapted from investigator's abstract): Use the investigator's abstract if possible. If the description is written in other than third person, it must be converted to third person.
- CRITIQUE: Discuss the strengths and weaknesses of the proposed project. Are the aims logical? Is the approach valid and adequate? Are the proposed procedures feasible and appropriate? Will the research produce new data and concepts or confirm existing hypotheses? What is the significance and pertinence of the proposed study in relation to the state of the field and the importance of the aims? For continuation and supplemental requests, comment on past progress. The Critique must reflect the priority score.
- INVESTIGATOR: Discuss the competence and background of the principal investigator. Do not discuss or make reference to his or her age, sex, race, or national origin.
- RESOURCES AND ENVIRONMENT: Discuss the facilities, the equipment, and, when appropriate, the extent of departmental and interdepartmental cooperation. Comment on the availability of any unusual resources, such as special animal species, tissue preparations, or clinical case material. This section is not needed if the resources and environment are adequate and there are no special features to be noted.
- BUDGET: Comment on whether the budget is realistic in terms of the aims and methodology. Also note whether all items are justified on the basis of the approach, procedures, and analysis of data proposed. Itemize and provide specific reasons for any reductions you suggest in time or amount. For supplementary requests, comment on the requested budget in relation to the approved parent budget.

OTHER POSSIBLE SECTIONS:

- HISTORY: An involved explanation or description of the administrative background may be included as a special section following the resume.

- CRITIQUE (MAJORITY). This heading is used only when a split vote is registered on the summary face page as a special note.
- CRITIQUE (MINORITY): Include a minority report when two or more members disagree with the recommendation.
- HUMAN SUBJECTS: If human subjects code indicates concerns or comments, discuss the topic in question. The correct numerical code should appear on the top of the summary statement. Any code other than 10, 30, 45, or an exemption code requires a section, addressing the specific problem requiring such a code, at the end of the summary statement.

A more detailed explanation of involvement of human subjects is found in Chapter XV, Section E.

- ANIMAL WELFARE: Concerns or comments indicated by the animal welfare code are discussed in this section. Any numerical code other than 10, 30, or 45 appearing on the top of the summary statement requires a section addressing the specific problem requiring such a code, at the end of the summary statement. The heading for this section is ANIMAL WELFARE CONCERN (or COMMENT).
- CRITERIA FOR FOREIGN AWARD
See Section D, Special Notes in this chapter.

For additional information concerning other types of summary statements, refer to the guidelines in Chapter V.

F. GUIDE FOR MULTIPROJECT APPLICATIONS (See Chapter XIII.)

G. ROSTER

A roster of the study section is included at the end of the summary statement. The roster is prepared according to Procedures for Creating on-Line Summary Statement File. The names of those present at the meeting should be listed. Do not include regular members who are absent from this particular meeting. (See sample, Chapter VII.)

H. SPECIAL CASES

1. Deferred Applications (To next Council)

On the summary statement printout for a deferred application, the Grants Assistant types either DEFERRED FOR PROJECT SITE VISIT or DEFERRED FOR ADDITIONAL INFORMATION as a special note. The original summary statement top should be sent to the appropriate Institute and a duplicate kept in the study section file. For applications with dual assignments, a copy of the top should also be sent to the secondary Institute.

There will be no text on a deferred summary statement.

2. Deferral for Mail Ballot

The summary statement will show the recommendation as DEFERRAL. The Executive Secretary then writes to the principal investigator to request the needed information. After the information has been received, it is sent to the reviewers. The reviewers' written comments and a ballot, which includes room for the vote (approval or disapproval), a priority score (for approvals), and any remarks, are then sent to the members of the study section. After a recommendation is received, the summary statement is completed in the usual manner and duplicated.

3. Revised or Corrected Summary Statements

If the summary statement must be retyped and redistributed, the word "REVISED", the date, and "See Note" should appear immediately under the identifying number of the summary statement (as if it were a special note). The appropriate Institute(s) should be contacted about the revised summary statement.

I. DISTRIBUTION OF TYPED COPIES

After checking the four copies received from the laser for accuracy, the Grants Assistant orders printed copies as instructed by the IRG Interface System (Function Number 71), available from the User Resource Office; keeps one copy in the study section office as a back-up copy; and distributes additional copies to the Lead Grants Technical Assistant and the appropriate Institute(s).

J. PRINTING SPECIFICATIONS AND DISTRIBUTION

The guidelines below explain paper colors:

- Research grant (all R's): pink
- Research Career Development Awards (K04 and K08): blue
- Program projects/centers/facilities (P01, P41, S10, etc.): salmon
- Fellowships (F32, F05, F06, F33): yellow

To prepare the requisition for printing, follow the directions found in the printout of instructions for IRG Interface System (Function Number 71 in the Division of Research Grants Information System). Distribution will be done by the Print Shop.

STUDY SECTION MINUTES AND CONFLICT OF INTEREST

A. SUMMARY MINUTES

The Grants Assistant prepares summary minutes for every meeting, including ad hoc meetings, for an annual report to the Library of Congress. The format is shown in Figure 63. The roster of study section members, including any special reviewers, the Executive Secretary, and Grants Technical Assistant (optional) is attached to the summary minutes. If the Grants Technical Assistant's name is on the roster, it is not listed in the summary minutes.

1. Preparation

The left and right margins should be 1 inch, wide enough for punching and binding. Minutes are typed on 8½ X 11 inch white paper. Whenever possible, avoid an extra sheet with only a few lines of type.

Names of Institutes, organizations, and Government agencies should be spelled out the first time used; initials may be used thereafter. Do not, however, use the letters that appear in the application number as the initials for an Institute, e.g., do not use HL for NHLBI. "United States" is spelled out when used as a noun, but the initials are used for adjectives, e.g., U.S. Government. Do not include titles of personnel outside of DRG.

2. Approval

- a. Chartered Study Sections: Summary Minutes, along with the statistics page (Figure 64), should not be duplicated until approved by the appropriate Lead Grants Assistant and certified, first by the Executive Secretary and then by the Chairperson of the study section. The originals of the minutes and roster must be forwarded to the Committee Management Office after certification.
- b. Ad Hoc Meetings: Minutes are required, but do not have to be signed or certified. The Committee Management Office needs the original of the minutes and rosters for all ad hoc meetings, but not the resume or statistical pages.
- c. Telephone Conferences: Minutes are not required for telephone conferences.

3. Distribution

Summary minutes are copied on 8½ X 11 inch white paper. Attachments are not backed and are included after the last page of the minutes. To determine the distribution of summary minutes see the Distribution Chart (Chapter V, Figure 36).

B. COMPLETE MINUTES

The complete minutes consist of the following:

- Summary minutes of the study section meeting (including the roster),
- Resume of Recommendations (Figure 64), and
- Summary statements

One copy of the complete minutes is to be retained and labeled as a file copy. Two sets should be available at the next study section meeting for members to examine if they wish. After the meeting, these extra sets of minutes are to be destroyed. Other distribution should be made in accordance with the latest Distribution Chart (Chapter V). The file copy of the summary minutes, resume, and summary statements must be discarded after three years.

C. CONFLICT OF INTEREST STATEMENTS

Two conflict of interest lists must be obtained by all study sections and retained in the study section files. They are listed below.

- All members must certify that they did not participate in the review of any application in which they had a possible conflict of interest (Figure 65).
- A list must be prepared indicating which members left the room because of conflict of interest during the review of applications (Figure 66).

SUMMARY OF MINUTES

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
DIVISION OF RESEARCH GRANTSPATHOLOGY A STUDY SECTION
SUMMARY OF MINUTES
JUNE 5-7, 1985

The meeting of the Pathology A Study Section was convened at 8:00 a.m., on June 5, 1985, in the Club Room, Westpark Hotel, Rosslyn, Virginia. In accordance with Public Law 92-463, the meeting was open to the public from 8:00 a.m. to 8:45 a.m. on June 5. A list of members and special reviewers is attached. Others in attendance were Dr. Nathan Watzman, Division of Research Grants; Drs. Anthony Kalica and Alfred Small, National Heart, Lung and Blood Institute; Dr. Colette Freeman, National Cancer Institute; and Dr. C. E. Phillips, National Institute of Neurological and Communicative Disorders and Stroke.

The members approved the minutes of the previous meeting; and set the following tentative dates for future meetings: October 16-18, 1985, February 19-21, 1986, and June 18-20, 1986.

In accordance with provisions set forth in Section 552b(c) (4) and 552(c) (6), Title 5, U. S. Code, and Section 10(d) of P.L. 92-463, the remainder of the meeting was closed to the public for the consideration of Research Grant and Research Career Development Award applications. There was a brief discussion of the review procedures and a reminder of the confidentiality of all information pertaining to the review of applications. Consultants were required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest. A list of these members is attached to the Study Section file copy of the minutes.

The Pathology A Study Section reviewed 86 Research Grant applications requesting \$30,704,349 support. The members favorably recommended 75 applications and \$21,799,485 support; and recommended disapproval of 11 applications requesting \$2,077,812. In addition, the Study Section reviewed three Research Career Development Award applications requesting \$777,464 support; three applications were favorably recommended. Also reviewed was one application for Special Foreign Currency Award (PL-480); it was recommended for disapproval.

The Study Section meeting was officially adjourned at 1:30 p.m. on Friday, June 7, 1985.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

John Green, Ph.D. (Date)
Executive Secretary

Sally Brown, Ph.D. (Date)
Chairperson

RESUME OF INITIAL REVIEW GROUP RECOMMENDATIONS
(PRIVILEGED COMMUNICATION)

SUMMARY STATISTICS

REVIEW GROUP: PATHOLOGY A STUDY SECTION

COUNCIL DATE: JAN./FEB. 1987
MEETING DATE: OCT./NOV. 1986

| | | |
|---|-------|------------|
| TOTAL NUMBER OF APPLICATIONS REVIEWED..... | 90 | |
| TOTAL NUMBER OF APPLICATIONS APPROVED..... | 85 | |
| PERCENT OF APPLICATIONS APPROVED..... | 94.4% | |
| TOTAL NUMBER OF APPLICATIONS DISAPPROVED..... | 4 | |
| PERCENT OF APPLICATIONS DISAPPROVED..... | 4.4% | |
| TOTAL NUMBER OF APPLICATIONS DEFERRED..... | 1 | |
| PERCENT OF APPLICATIONS DEFERRED..... | 1.1% | |
| MEAN PRIORITY SCORE..... | 229 | |
| PRIORITY RANGE | 103 | 414 |
| TOTAL DOLLARS REVIEWED..... | | 43,481,566 |
| TOTAL DOLLARS APPROVED..... | | 34,370,693 |
| TOTAL DOLLARS DISALLOWED (APPROVED APPLICATIONS)..... | | 6,622,586 |
| TOTAL DOLLARS DISAPPROVED..... | | 1,848,531 |
| TOTAL DOLLARS DEFERRED..... | | 639,756 |

FIGURE 64

CERTIFICATION OF NO CONFLICT OF INTEREST

This will certify that in the review of applications conducted by the (Study Section) on (date), I absented myself from the room during the review of any application from an organization, institution, or university system where I am an employee, consultant, officer, director or trustee, or have a financial interest. I was not present during the review of any application when my presence would have constituted a real or apparent conflict of interest.

(Signature and Typed Name)

(Signature and Typed Name)

LIST OF MEMBERS ABSENT DURING REVIEW OF APPLICATIONS

During the review of the following applications at the _____
Study Section meeting from (inclusive dates), the members noted were absent
from the room because of a conflict of interest:

| <u>Application No.</u> | <u>Study Section Member</u> |
|------------------------|-----------------------------|
| 1 R01 AI 12345-02 | Dr. Wilkinson |
| 1 K04 AI 00105-01 | Dr. Wilkinson |
| 1 R01 AM 18333-01 | Dr. Woolley |
| 2 R01 CA 12164-04 | Dr. Woolley |

TRAVEL ORDER

FIGURE 67

APPROPRIATION NO

☐ Original ☐ Amendment No. _____ ☐ Cancellation
(See HHS Travel Manual, Part 4, for Detailed Instructions)

4 NAME AND POSITION OR RANK

5 SSAN

6 CONSTITUENT/BUREAU/DIVISION/REGION

7 PRESENT OFFICIAL STATION

8 ITINERARY AND PURPOSE OF TRAVEL (Show city, state or country, dates and reasons - use continuation sheet if necessary)

3 ESTIMATED COST

| | TO DHHS | TO OTHERS |
|----------|----------|-----------|
| TRAVEL | \$ _____ | \$ _____ |
| PER DIEM | _____ | _____ |
| OTHER | _____ | _____ |
| TOTAL | \$ _____ | \$ _____ |

8. APPROX DATE OF DEPARTURE

9. APPROX DATE OF RETURN

11 SPECIAL AUTHZTN
TRAVEL BY PRIVATELY OWNED AUTO IS AUTHORIZED ON MILEAGE BASIS RATE SPECIFIED BELOW FOR
☐ EMPLOYEE AND/OR ☐ DEPENDENTS
_____¢ PER MILE AS MORE ADVANTAGEOUS TO GOVT _____¢ PER MILE NOT TO EXCEED COMMON CARRIER COSTS _____¢ PER MILE NOT TO EXCEED COSTS BY GOVT OWNED AUTO
☐ GSA AUTO ☒ AUTO RENTAL UNDER GSA CONTR ☐ OTHER (Specify below)
☐ EXCESS BAGGAGE ☐ REGISTRATION FEE

2 TRAVEL & PER DIEM IS AUTHORIZED IN ACCORDANCE WITH DHHS POLICY AND

☐ SGTR'S ☐ JTR'S ☐ FSR'S ☐ OTHER (Specify)

PER DIEM: ☐ NONE ☐ IN U.S. ☐ OUTSIDE U.S. ☐ VARYING RATES PER ABOVE REGS
RATE \$ _____ ☐ LODGINGS PLUS ☐ ACTUAL EXPENSE ☐ FIXED

4 ACCOUNTING DATA (See HHS Acct'g Manual & Acct'g Code Book)

| 1 | 27 EFF DATE | 8-10 TRANSACTION CODE | 11-12 REVERSE CODE MODIFIER | ORIGINAL OBLIGATION DOC | | OTHER DOCUMENTS | | 39-40 GEO CODE FISCAL YEAR | 41-47 COMMON ACCOUNTING NO | 48-51 OBJ CLASS CODE | 52-63 AMOUNT DOLLARS & CENTS | 64 FEDINON FED | 65-79 VENDOR CUSTOMER CODE (PRIMARY RECIPIENT) | 95-100 PAYMENT COLLEC TION DOC | 101-106 PPBS | | 107-108 CATE- GORY | 109 ACTIV ITIES CASE II |
|---|-------------------|-----------------------------|-----------------------------------|-----------------------------|-------------------------|-----------------------------|-------------------------|----------------------------------|-------------------------------------|-------------------------------|---------------------------------------|-------------------|--|--|--------------------------|---------------------------|--------------------------|----------------------------------|
| | | | | 13-15 DOC REF CODE | 16-25 DOCUMENT NO | 26-28 DOC REF CODE | 29-38 DOCUMENT NO | | | | | | | | 101-106 CATE- GORY | 107-108 ACTIV ITIES | | |
| 2 | | | | 130 | | | | 1 | | | | 1 | | | | | | 2 |
| 2 | | | | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | | | | |

5 NAME AND TITLE OF OFFICER RECOMMENDING ABOVE TRAVEL

AUTHORITY IS HEREBY GRANTED TO PERFORM TRAVEL AND TO INCUR SUCH EXPENSES AS MAY BE NECESSARY UNDER THE CONDITIONS SET FORTH ABOVE

AUTHORIZED BY

TITLE.

DATE.

* To be completed by Office Initiating Travel Order. Other Accounting Data to be completed by Financial Accounting Office.

FIGURE 68

| | | | | | |
|--|--|---|--|--|--|
| 1 VOUCHER Privacy Act on the back) (Last, first, middle initial) | | 2. TYPE OF TRAVEL <input type="checkbox"/> TEMPORARY DUTY <input type="checkbox"/> PERMANENT CHANGE OF STATION | | 3 VOUCHER NO 4. SCHEDULE NO. | |
| 5. HOME ADDRESS (Include ZIP Code) | | b SOCIAL SECURITY NO | | 6 PERIOD OF TRAVEL a FROM b TO | |
| 7. HOME PHONE ADDRESS | | d OFFICE TELEPHONE NO | | 7 TRAVEL AUTHORIZATION a. NUMBER(S) b. DATE(S) | |
| 8. HOME DUTY STATION | | i RESIDENCE (City and State) | | 10. CHECK NO. | |
| 9. ADVANCE a. DATE RECEIVED b. AMOUNT RECEIVED \$ c. PAYEE'S SIGNATURE | | 9. CASH PAYMENT RECEIPT | | 11. PAID BY | |
| 12. STATEMENT OF ASSIGNMENT I hereby assign to the United States any right I may have against any parties in connection with reimbursable transportation charges described below, purchased under cash payment procedures (FPMR 101-7) | | 13. TRAVELER'S INITIALS | | 14. POINTS OF TRAVEL FROM (e) TO (f) | |
| 15. AGENT'S VALUATION OF TICKET (a) | | 16. ISSUING CARRIER (Initials) (b) | | 17. MODE CLASS OF SERVICE AND ACCOMMODATIONS (c) | |
| 18. DATE ISSUED (d) | | 19. DATE | | 20. AMOUNT CLAIMED \$ | |
| 21. VOUCHER IS APPROVED Long-distance telephone calls, if any, are certified as in the interest of the Government (NOTE: If long distance telephone calls are made, the approving official must have been authorized in writing by the department or agency to so certify (31 U.S.C. 680a).) | | 22. FOR FINANCE OFFICE USE ONLY COMPUTATION a. DIFFERENCES, IF ANY (Explain and show amount) | | 23. TOTAL VERIFIED CORRECT FOR CHARGE TO APPROPRIATION Certifier's initials. | |
| 24. PRECEDING VOUCHER PAID UNDER SAME TRAVEL AUTHORIZATION a. NO b. D.O. SYMBOL c. MONTH & YEAR | | 25. APPLIED TO TRAVEL ADVANCE (Appropriation symbol): | | 26. NET TO TRAVELER \$ | |
| 27. PRINTING CLASSIFICATION | | 28. DATE | | 29. NET TO TRAVELER \$ | |

Complete this PAGE
information _____ OF _____ PAGES
if this is a continuation
other

TRAVEL AUTHORIZATION NO

TRAVELER'S LAST NAME

Complete this PAGE
information _____ OF _____ PAGES
if this is a continuation
other

TRAVEL AUTHORIZATION NO

TRAVELER'S LAST NAME

215

| | |
|--------------------|--|
| SUBTOTALS ▶ | |
| TOTALS ▶ | |

Enter grand total of columns (i), (m) and (n), below and in item 13 on the front of this form

| | | | | | |
|--|--|---|--|--|---------------------------------|
| ADVANCE OF FUNDS APPLICATION AND ACCOUNT <input type="checkbox"/> CASH <input type="checkbox"/> TEMPORARY <input type="checkbox"/> TELEPHONE <input type="checkbox"/> PERMANENT | | 3 NAME LAST, FIRST, MIDDLE INITIAL 5 TELEPHONE NUMBER(S) | | 4 ACCOUNT NO 6 SOCIAL SECURITY ACCOUNT NO | |
| 1 TYPE OF ADVANCE 2 TYPE OF TRAVEL | | 7 DEPARTMENT OR ESTABLISHMENT | | 8 BUREAU DIVISION OR OFFICE | |
| 9 APPLICATION — For completion by applicant An advance of funds is hereby requested for travel and other expenses to be incurred by me. | | | | | |
| 10 UNDER AUTHORIZATION NUMBER | | 11 DATE OF AUTHORIZATION | | 12 BALANCE DUE U.S. FROM PREVIOUS ADVANCE | |
| 13 TOTAL | | 14 AMOUNT HEREIN APPLIED FOR | | 15 | |
| 16 TRAVEL PERIOD | | | | | |
| 17 MAIL CHECK TO <input type="checkbox"/> OFFICE <input type="checkbox"/> RESIDENCE Give address — number, street, city, State, ZIP code. | | | | | |
| Note: Outstanding advances not fully recovered by deductions from reimbursement vouchers must be promptly repaid. When travel is canceled or indefinitely postponed, the full amount of any outstanding advance shall be repaid immediately. | | | | | |
| 18 APPLICANT SIGN HERE | | | | | 19 DATE |
| 20 SIGNATURE AND TITLE OF APPROVING OFFICIAL | | | | | 21 DATE APPROVED |
| 22 APPROPRIATION TO BE CHARGED | | | | | 23 |
| 24 REMARKS | | | | | 25 CASH PAYMENT RECEIVED |
| 26 | | | | | 27 DATE |

[illegible]

FIGURE 73

| | | | | | |
|--|--|--|--|----------------|------------------|
| 6. EMPLOYEE NAME AND TITLE, REASON FOR ATTENDANCE, AND JUSTIFICATION (ATTENDANCE MUST BE ADVANTAGEOUS TO THE DEPARTMENT) | | 7. ESTIMATED COST REGISTRATION FEE | | TAXICAB FARE | OTHER (Identify) |
| SPONSORING ORGANIZATION OR GROUP, PLACE AND DATES OF MEETING (USE SEPARATE SHEET, IF NEEDED) | | ATTENDANCE AT MEETING(S) FOR THE ABOVE NAMED EMPLOYEE(S) IS HEREBY AUTHORIZED AS PRESCRIBED BY THE NEW TRAVEL MANUAL | | SUB-TOTAL | |
| | | | | TOTAL (Item 7) | |
| | | | | | |
| AUTHORIZED BY: _____ TITLE: _____ | | AUTHORIZED BY: _____ TITLE: _____ | | DATE: _____ | |

SPECIAL STUDY SECTION

A. INTRODUCTORY COMMENTS

A Special Study Section is an ad hoc group convened, generally for only one meeting, to review one or more applications. The group normally consists of five or more members, the exact number depending on the size, complexity and number of the applications being reviewed. The Special Study Section is managed by an Executive Secretary chosen from among the staff in the Special Review Section (SRS) or an Executive Secretary from another DRG Study Section.

1. Project Review and Assignment

There can be several reasons for assignment of a grant application to a Special Study Section: to handle special considerations, review special programs, or avoid conflicts of interest.

a. Special Considerations: Some circumstances necessitate a special review, for example, when the research area of a proposed project is outside the expertise of a chartered study section, or when the multidisciplinary nature of an application exceeds the scope of a chartered study section. Unusual collaborative arrangements or budget complexities may also necessitate review by a Special Study Section. An application may also be assigned to a Special Study Section for review in response to an applicant's documented objection that a previous review was flawed, or if there is a probability of interpersonal conflict with any member of the appropriate chartered study section.

b. Special Programs. The special programs of various Institutes of the NIH are often reviewed by a Special Study Section. These include some applications in response to a Request for Applications (RFA) as well as those for a Biotechnology Resource Grant (P41 or R24), a Cooperative Agreement (U01), a Program Project Grant (P01), a Shared Instrumentation Grant (S10), or a Small Business Innovation Research Grant (R43 or R44).

c. Conflict of Interest. In certain instances, applications are reviewed by a Special Study Section in order to avoid an actual or potential conflict of interest. Most often this happens when an applicant or the applicant's spouse, parent, or child, or close professional associate is a member of the chartered study section. The application must then be reviewed either by another study section with appropriate expertise or by a Special Study Section. For Special Study Section reviews of chartered study section members, no more than 50 percent of the reviewers may be members of the original study section, a member of the original study section may not chair the review meeting, and the Executive Secretary of the member's study section may not manage the review.

B. ADMINISTRATION

1. General

Applications assigned to the Special Study Section (SSS)* for review are subject to the same review deadlines and policies as applications reviewed by chartered study sections. Any questions should be directed to the Office of the Chief, Special Review Section, RRB.

When an Executive Secretary receives the assignments, the Grants Assistant will aid the Executive Secretary in all aspects of the review. The Grants Assistant obtains from the Executive Secretary information regarding the applications to prepare needed study section material(s) for use by the Executive Secretary. After the meeting, the Grants Assistant prepares and enters data for entry to the IMPAC system in order to have this information available for retrieval by the Institute(s) as soon as possible.

In all matters pertaining to SSS review, only the following identification should be used:

Executive Secretary
Special Study Section
Referral and Review Branch
Division of Research Grants

2. Information Needed by the Special Review Section Prior to Review

- The date, time and location of the SSS meeting and/or site visit.
- One copy of the roster of the SSS meeting and/or site visit team.

3. Information Needed by the Special Review Section After Review

- One copy of the laser summary.

* Not to be confused with the code SRC, which refers to a Special Review Committee of an Institute.

C. REVIEW

1. Study Section Membership

a. Composition. A minimum of five consultants are needed to review an SSS application. A larger number may be necessary for more complex applications. For program projects and centers, a fiscal consultant may be included as a member of the Special Study Section. One of the consultants is designated as Chairperson and assumes responsibilities similar to that of the Chairperson of a chartered study section.

b. Procedures. When an application from a member of a chartered study section is assigned to an SSS, the responsible Executive Secretary should request input from the Executive Secretary of the member's study section. Also, if a potential consultant is a current member of an Institute review group, the SSS Executive Secretary should first contact the Executive Secretary of that study section before extending an invitation.

Only one consultant from an institution is permissible on an SSS review. A consultant from a state system with several campuses may not review an application from any campus in that system; however, one consultant from each campus may be on the Special Study Section to review applications outside the state system.

When an application is being reviewed from an institution with multiple campuses, an SSS panel member may not participate in the review of that application and must leave the meeting room if he or she is from any campus in that system (if not exempt). Study section members are required to leave the room during the review of any application from an organization for which the reviewer is an employee, consultant, officer or trustee, or has a financial interest. The above constitutes a conflict of interest and is illegal.

c. Roster. The roster, which is included as the last page of the summary statement, is prepared by the Grants Assistant. It includes the consultants' title(s) as well as department(s) and school affiliation(s), but no mailing address (i.e., P. O. Box or Streets, etc., or telephone numbers). The roster should identify the Executive Secretary, Grants Assistant and any Institute personnel attending the site visit or meeting. One copy of the completed SSS roster should be forwarded to the Chief, Special Review Section. The Certification of No Conflicts of Interest should be signed by all members at the meeting. (See Chapter XI, Figure 65.)

The Certification of No Conflict of Interest statement is as follows:

Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.

2. Staff Liaison

Liaison with program staff of an Institute should be initiated when the review committees are being formed. In the case of larger proposals, in particular, it is essential that the Institute(s) concerned have ample time to inform the necessary staff of meetings and/or site visits.

3. Privacy Act

A Privacy Act Statement (Figure 74) is normally included with mailings to SSS members. However, if the Guide for Reviewers' Preliminary Comments is sent to the Study Section, this Statement is not needed. Inquiries for summary statements after the review are handled in the same manner as inquiries on chartered study section reviews.

4. Orientation Document

The Special Review Section has prepared a brief orientation document, which may be included in mailings to consultants. This document is available in the Special Review Section.

5. Project Site Visits and SSS Meetings

a. General. Assigning an application to SSS does not imply that a site visit is required. The rationale for a site visit should be referred to within the summary statement. A separate paragraph may be added at the end of the summary statement (optional) with the heading "PROJECT SITE VISIT," if the Executive Secretary feels the site visit information would add to the discussion of the review.

In general, consultants should meet away from the university or institution being visited. If a hotel conference room is rented, the fee will be charged to the Scientific Review and Evaluation Award of the study section paying the consultants' expenses.

The Institute(s) may send a staff member as an observer.

b. Mail Ballots. Mail ballot reviews should not be used without prior discussion with the Chief, Special Review Section, RRB.

c. Conference Call Review. Special Study Sections may also be convened using a telephone conference call, depending on the nature of the application being reviewed and the circumstances necessitating a special review. Experience has shown that for selected applications a telephone conference can provide a thorough and competent review at greater convenience to the reviewers and less cost to the Government.

The Executive Secretary contacts the consultants, sets a date and time for the conference call, and obtains a phone number where they may be reached. After the date is confirmed, the Grants Assistant calls the NIH operator (dial 106) or other telephone conferencing

services to set up the conference. The Special Review Section can provide information regarding alternate resources for a conference call (Figure 75). Charges for use of a non-government telephone conferencing service will be paid from the Scientific Review and Evaluation Award.

In addition to the normal correspondence and materials, the Grants Assistant should send the consultants a Certification of No Conflict of Interest Statement and Claim for Reimbursement of Travel Cost, Per Diem and Consultant Fee (Figure 76). They may receive a \$100.00 consultant fee for participating in the conference call review. A memo is sent through the Chief, Special Review Section to the DRG Budget Office requesting that the members be paid for their participation (Figure 77).

d. Research Grant Applications. The location of the SSS meeting should be economical for NIH, reasonably convenient for the consultants involved, but most important, appropriate for the best scientific review of the application. If a site visit is required, the SSS meeting should immediately follow the site visit. A pre-site visit meeting may be necessary prior to the site visit for orientation and discussion. On some occasions it is possible to complete the site visit, the SSS meeting, and preparation of the draft report on the same day. The Special Review Section will provide information on the procedures for these site visits.

6. Reporting Actions after the Meeting

After the study section meeting, the Grants Assistant enters the necessary data (budget, priority score, human/animal subject(s) codes) into the computer system. Any changes that need to be made are the responsibility of the Grants Assistant. See Chapter X for more detailed information on the preparation of summary statements.

After the summary statement is typed and proofread, the Grants Assistant will provide discs to the User Resource Office, and then order from the Print Shop sufficient copies for the Institute(s) and the official file.

Resume of Recommendations

Grants Assistants will request an individual resume.

7. Reimbursement to Consultants

Review costs are charged to Scientific Review and Evaluation Awards. The Grants Assistant prepares the Claim for Reimbursement in the same manner as for a chartered study section. It is important, however, that the voucher be properly identified. Thus, SSS and the flex code should be placed in parentheses after the chartered study section name on the voucher, e.g., ALY(SSS-0). Information on the SSS consultant is coded on the reimbursement form in compliance with travel guidelines. The Grants Assistant handles the return of these vouchers in the same manner as for vouchers from chartered study section members.

8. Travel Orders

Travel orders for the Executive Secretary or other Civil Service personnel for SSS reviews are approved by the Assistant Chief, Special Review Section, and routed as follows:

Chief, Special Review Section (Room 2A16, Westwood Bldg.)
Travel Office, (Room 455, Westwood Bldg.)
Chief, Administrative Branch (Room 448, Westwood Bldg.)
Travel Office, (Room 455, Westwood Bldg.)

9. Study Section File

The file should contain only items generally retained in a study section file: 3 copies of the application currently under review, 10 copies of the current summary statement, and 1 copy of any previous application and summary statement. These files should be complete and orderly.

10. Forms

In addition to the forms and guidelines included in this chapter, guidelines exist for special Institute programs, such as the Biotechnology Research Resource Program. These may be obtained through the Office of the Chief, Special Review Section.

For all of the SSS forms and guidelines, the Grants Assistant is responsible for duplicating the number of copies needed.

Privacy Act Statement

SPECIAL STUDY SECTION REVIEWERS

Under the Privacy Act of 1974 (P.L. 93-579), and implementing regulations, the principal investigator (program director, candidate) may request and receive a copy of your written comments. After incorporation of information from these comments into the summary statements, documents you provide are not retained.

In the event that review comments identifying you as the author are made available to the principal investigator (program director, candidate), you will be promptly notified by the National Institutes of Health staff. Further information can be obtained from the Executive Secretary in charge of the review.

CONFERENCE CALLS

The Grants Assistant makes the necessary calls to arrange a Telephone Conference. This call should be made as soon as a firm date is available to reserve a block of time to do the review. Upon completion of the call to the conference service you will be given a "call back" number which you will relay to your reviewers. They will call "collect" to that number and as soon as all participants are "on line" the Executive Secretary starts the Conference Call by giving all participants the necessary introductory remarks then the call can proceed.

One such Conference Service is:

American Teleconferencing Service
8686 College Blvd - Suite 115
Overland Park, KS 66210

913-661-0700

FIGURE 76

Submit in TRIPLICATE. Please read carefully, including information on reverse: (1)

| | | |
|--|--|------|
| DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH CLAIM FOR REIMBURSEMENT OF TRAVEL COST, PER DIEM, AND CONSULTANT FEE | | DATE |
| NAME OF CHAIRMAN (2) | STUDY SECTION, REVIEW GROUP OF COMMITTEE (3) | |

PLACES AND DATES OF ASSIGNMENT

(4)

(5)

(6)

TRAVEL ITINERARY

NOTE: In cases of combined personal and official business during the same trip, show departure and return time that could have been followed for the sole purpose of this assignment. Take this into account in itemizing expenses below.

LEFT (City, date, hour)

DATE OF MEETING(S) OR SITE VISIT(S)

RETURNED (City, date, hour)

TRAVEL EXPENSES

(A) Cost of transportation (receipts required). If mixed mode of travel, indirect routing, or stopovers for personal reasons are involved, claim only cost of usual direct-route round trip fare. If travel is by privately owned plane, 24¢ an air mile is allowed, or by private auto, (7) ¢ a mile (not to exceed cost by common carrier) will be allowed.

Sesadometer Readings

\$

(B) Taxi or limousine used for official business, including up to 15% for tips. (Receipts not required.)

\$

(C) Other (Examples: Road and bridge tolls, parking, telegram and telephone calls for official business, conference room rentals.) Receipts required only on items costing \$15 or more. Flight or other travel insurance is considered a personal expense and is not reimbursable.

\$

Identify claims

(D) TOTAL TRAVEL EXPENSES →

(E) Lodging. Itemize each day's meal and lodging costs (including tax). This information is needed to determine the appropriate per diem allowance under the "Lodging Plus" system, and the "Actual Expense" method. (See reverse.)

| DAY | DATE | LODGING | BREAKFAST | LUNCH | DINNER | TOTAL |
|-----|------|---------|-----------|-------|--------|-------|
| 1ST | | \$ | \$ | \$ | \$ | \$ |
| 2ND | | | | | | |
| 3RD | | | | | | |
| 4TH | | | | | | |
| 5TH | | | | | | |

If unusual circumstances regarding an assignment affect your claim, check this block and explain on reverse side in REMARKS. ☐

STATEMENT OF PERSONAL SERVICES

I certify that the above itemization reflects costs incurred for official business and that I provided consultant services in connection with this assignment on the dates indicated.

HOME ADDRESS

ADDRESS (Where check is to be mailed if other than home)

SOCIAL SECURITY NO. (See Privacy Statement on reverse)

SIGNATURE OF CONSULTANT

THIS SECTION FOR NIH USE ONLY

1. I certify that the above Consultant is entitled to a consultant fee for _____ days at \$100 per day.

\$

Signature of Executive Secretary:

(8)

2. Per diem _____ days at \$ _____ per day and/or Actual & Necessary (as determined by Item E)

\$

3. Travel (from Item D, above)

\$

ADVANCE DEDUCTED (When Applicable)

4. TOTAL TO BE PAID →

\$

Pre-audited by

Approved by

CLAIM FOR REIMBURSEMENT OF TRAVEL COST, PER DIEM, AND CONSULTANT FEE
(NIH 1715-2)

Completion of Consultant Voucher for Special Study Section Review.

- ITEM 1. Complete name of the consultant.
- ITEM 2: Name of the Chairman of the study section that is being charged for this Special Study Section review.
- ITEM 3: Code for the Study Section that is being charged.
(Example) The code ALY(SSS) flex code.
- ITEM 4 Place where the review was held.
- ITEM 5. Identification of the review. This can be the name of applicant, grant number, or name of package by scientific discipline.
- ITEM 6. Date of meeting.
- ITEM 7. Current rate allowed for travel by private auto.
- ITEM 8: Name of the Executive Secretary. The Executive Secretary will also need to sign here to verify the number of consultant days.
- ITEM 9. "G" if the Consultant is an ad hoc member.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
National Institutes of Health

November 1, 1986

Executive Secretary, Special Study Section

Reimbursement for Telephone Conference Call Review
Chief, Special Review Section, DRG

Budget Office, DRG

The roster attached identifies the telephone conference.

Date of Conference Call Review _____

Principal Investigator _____

Application number(s) _____

Number of consultants participating _____

Number of consultants participating by phone _____

Origin of phone call or location of meeting _____

Justification for conference call review _____

Economic benefit to the Government. Savings
in Chairman's grant funds, reviewers travel
time and convenience of Executive Secretary.

Executive Secretary

Attachment
(One copy of roster)

INSTITUTE RELATIONSHIPS

A. ROLE OF THE NIH INSTITUTES IN THE REVIEW OF GRANT APPLICATIONS

In the NIH peer review system, an Institute provides the second level of review of most grant applications. This review, which occurs after the study section has completed its review of the scientific and technical merit of an application and has presented its recommendation to the Institute in a summary statement, is performed by the Institute's Council. Funding is done through the Institute.

Institute staff members are responsible for handling correspondence with investigators after the study section review has been completed. Copies of this correspondence are routinely forwarded to the appropriate study section. Institute staff duties include sending summary statements to all applicants before Council, notifying the applicants of the fate of their applications after Council, answering inquiries about the reasons for the actions taken, handling rebuttal letters, negotiating changes in budgets, giving tentative approval to changes in principal investigators, arranging for transfer of support between institutions, and reviewing annual progress reports. While Institute staff may consult with an Executive Secretary before taking the above actions, the final decision rests with the Institute.

Institute staff are also responsible for notifying Executive Secretaries of any problems with specific summary statements. Copies of summary statements with substantive problems (as contrasted with typographical or clerical matters) should be sent as soon as possible to the Chief, RRB, DRG with a brief description of the problem(s). If possible, such concerns should be sent prior to the summary statements being transmitted to the principal investigators. This process is only for the purpose of tracking the magnitude of summary statement problems; it does not abrogate the relationship between the Executive Secretary and Institute staff in the usual process for revising summary statements where justified.

B. MATERIALS REQUIRED BY INSTITUTES FROM STUDY SECTIONS

Summary statements, copies of all correspondence between the Executive Secretary and the principal investigator, the names of individuals from whom outside opinions were requested, human subject forms, and progress reports are sent to the assigned Institute. Outside opinions, however, are not sent to the Institute. A copy of the official project site visit report should be sent to the Institute but not copies of individual reports prepared by members of the site visit team. The written reviews that members of the study section prepare for study section meetings are never forwarded to the Institute; such comments are to be used only by the Executive Secretary in preparing summary statements.

C. MATERIALS REQUIRED BY STUDY SECTIONS FROM INSTITUTES

Institute staff are responsible for sending Executive Secretaries copies of the following documents when the documents are related to applications that were reviewed by their study sections:

- Written reports of administrative visits and program evaluations made by the Institute or Council;
- Correspondence; and
- Progress reports.

If a study section is assigned an application that was previously handled by an Institute committee, the Institute staff should supply all necessary background material and pertinent correspondence. Copies of previous applications and related summary statements should always be available in the Institute if needed by a study section.

After a grant is activated, some Institutes may send the study section a copy of the Notice of Grant Award, Form PHS 1533 (Figure 78), and all subsequent incoming and outgoing correspondence with the grantee. Any changes between the grantee and the Institute should be brought to the attention of the Executive Secretary. Whether or not the grant is still active can be determined from the status report.

D. INSTITUTE REPRESENTATION AT STUDY SECTION MEETINGS AND ON PROJECT SITE VISITS

Meeting agendas should be available in a timely fashion since a staff member from each Institute for which applications are being reviewed normally attends study section meetings in order to note the study section actions on relevant applications and to provide information on Institute policies and programs. Generally only one representative from an Institute attends a study section meeting.

Institute staff should be informed as soon as possible of plans for, and invited to attend, project site visits. Project site visits usually involve circumstances where the presence of an Institute staff member would be helpful to both the Executive Secretary and the Institute. The Institute representative attends as a resource staff member on Institute programs and policies.

E. ATTENDANCE OF THE EXECUTIVE SECRETARY AT COUNCIL MEETINGS

The Executive Secretary is expected to attend Council meetings at which applications reviewed by the study section will be evaluated. If a Council member requests additional information about a summary statement, the Executive Secretary may be called upon to comment. It is the responsibility of the Executive Secretary to provide all necessary information in support of the study section's actions.

An Executive Secretary must not provide Council with names of the individual study section members responsible for specific written

reviews, for motions, for seconds, or for specific comments in a summary statement. All study section actions are to be collective and anonymous. Generally, the term "reviewers" is used to describe all members, including those individuals who have provided outside opinions. The Council is entitled to know the distribution of individual priorities, but a specific priority must not be identified with a reviewer. Identification of outside reviewers is permitted, but the content of the reviews must not be disclosed.

NOTICE OF GRANT AWARD

TYPE OF AWARD RESEARCH
 AUTHORIZED BY 42 USC 241 42 CFR 52
 AWARDED BY

DATE ISSUED. March 26, 1985
 GRANT NUMBER
 TOTAL PROJECT PERIOD
 From 07/01/80 Through 03/30/8

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Title of Project or Area of Training

| | |
|--|--|
| Grantee Institution REGENTS OF THE UNIVERSITY CALIF UNIVERSITY OF CALIFORNIA 1483-4TH AVE SAN FRANCISCO, CALIF 94143 | Principal Investigator/Program Director/Awardee PHD UNIVERSITY OF CALIFORNIA CARDIOVASCULAR RESEARCH INST SAN FRANCISCO, CALIF 94143 |
|--|--|

| APPROVED BUDGET | | AWARD COMPUTATION | |
|---|-----------|----------------------------------|----------|
| FOR BUDGET PERIOD 04/01/85 Through 03/31/86 | | 1. DIRECT COSTS | \$ 63,16 |
| Salaries and Wages | \$ 41,709 | 2. INDIRECT COSTS | \$ ** |
| Fringe Benefits | 9,697 | (Calculated at _____ rate) | |
| Total Personnel Costs | \$ 51,406 | 3. TOTAL | \$ 63,16 |
| Consultant Costs | | 4. Less Unobligated Balance From | |
| Equipment | | Prior Budget Period(s) | \$ |
| Supplies | 7,579 | | |
| Travel - Domestic | 1,007 | | |
| - Foreign | | 5. AMOUNT OF THIS AWARD | \$ 63,16 |
| Patient Care - Inpatient | | | |
| - Outpatient | | | |
| Alterations and Renovations | | | |
| Contractual or Third Party Costs | | | |
| Other | 3,175 | | |
| Trainee Stipends | | | |
| Trainee Tuition and Fees | | | |
| Trainee Travel | | | |
| TOTAL DIRECT COSTS | \$ 63,167 | | |

When PHS Prior Approval is required for rebudgeting, submit request to Grants Management Official below.

REMARKS

**INDIRECT COSTS FOR THIS AWARD ARE EXPECTED TO BE \$ 19,329. ACTUAL INDIRECT COSTS WILL BE PROVIDED ON A SUMMARY NOTICE.

Staff contacts for this grant are:

Program : Dr. Everett Sinnett (301) 496-7171
 Grants Management: Mrs. Toni Holland (301) 496-7255

THIS AWARD IS FUNDED UNDER HHS SINGLE LETTER OF CREDIT NO. 75-08-1471.

TERMS OF ACCEPTANCE. By acceptance of funds awarded under this grant, the grantee acknowledges that it will comply with terms and conditions in the following: (1) Legislation cited above; (2) Regulations cited above; (3) Provisions on or attached to this award notice and signed by the official(s) named below; (4) PHS Grants Administration Manual Chapters in effect on the beginning date of the grant Budget Period; (5) PHS Grant Policy Statement in effect on the beginning date of the grant Budget Period; (6) 45 CFR Part 74. The above order of precedence shall prevail.

| | | | |
|--|---|--|-----------------------------------|
| FY - Common Accounting Number 5-8424151 | CRS/Entity Identification No. 1946036493A6 | PHS List No./Object Class Code /41.4E | Document Number (08)R3HL26176A |
|--|---|--|-----------------------------------|

PROGRAM OFFICIAL

Suzanne S. Hurd

SUZANNE S. HURD, PH.D.
 DIRECTOR
 DIVISION OF LUNG DISEASES
 NAT. HEART, LUNG, & BLOOD INST.

PHS Grants Management Official

James M. Pike

JAMES M. PIKE, CHIEF
 GRANTS OPERATIONS BRANCH
 DIVISION OF EXTRAMURAL AFFAIRS
 NAT. HEART, LUNG, & BLOOD INST.

PHS-1533
 Reproduced and distributed to Principal Investigator, Program Director or Awardee, and Business Office.

Chapter XV

AREAS OF SPECIAL CONCERN

A. CONFLICT OF INTEREST

1. Avoiding Conflicts of Interest in Study Section Assignments

A study section may not review an application in which one of its members is the principal investigator or is listed on the budget page in any capacity for compensation. In addition, when a member's spouse, parent, child or any family member is named in a grant application as the principal investigator, the member's study section may not review the application.

When the member is listed in any capacity, without monetary compensation, whether the application will be assigned to the study section depends on the Executives Secretary's judgment of the degree of responsibility the member will have in carrying out portions of the proposal. In addition, judgment must be exercised where the member's spouse, parent or child is named in a grant application in any capacity other than as the principal investigator. Also, when a close professional associate* is named in a grant application as the principal investigator or as an investigator who is responsible for conducting any portion of the planned research, further judgment is demanded to determine whether the member's study section may review the application. The decision is based on (1) the recency, frequency, and strength of the working relationship between the member and the associate as reflected, for example, in publications; and (2) the determination of whether the member has a vested interest or tangible involvement in the application. For example, a member and principal investigator, no longer at the same institution, may be publishing data generated together as former laboratory colleagues. While they appear as joint authors in the bibliography of the proposal, the member has no vested interest or tangible involvement in the application in question, and the member's IRG could review it; however, because of the appearance of conflict of interest, the member must leave the room during the review.

In general, the member's study section may review those applications in which the member has no apparent or real conflict. This would include the member being available at the principal investigator's institution for discussion; being a provider of services, cell lines, reagents, or other materials; or writing a letter of reference. In these cases, however, the member must be absent from the room during the review.

* "Close professional associate" is the term NIH finds most appropriate to the word "partner" in the Federal conflict-of-interest laws and regulations.

a. Flexible Study Sections. For a flexible study section, review by a subcommittee within the study section is permissible. Conflict of interest is avoided as long as the subcommittees of the flexible study section do not meet in a plenary session to ratify the recommendations of each group.

b. Individual and Senior (F32 and F33) Fellowship Applications. An application in which a member is named as sponsor may not be reviewed by the member's study section.

c. Applications from For Profit Organizations. A study section may not review an application from a member who is an owner or officer in a for-profit organization submitting the application.

NIH staff must not be involved in the review of an application in which they have a financial interest in a for-profit organization submitting an application, including ownership of stock in the for-profit organization. In such instance, an Executive Secretary must transfer the assignment and study section review responsibilities to another Executive Secretary.

2. Avoiding Conflicts of Interest During Study Section Meetings

At the beginning of each meeting, the Executive Secretary explains the NIH conflict-of-interest policy. Members must leave the room when applications submitted by their own organizations are being discussed or when they, their immediate family, or close professional associate(s) have a financial interest, even if no significant involvement is apparent in the proposal being considered. Members are also urged to avoid any actions that might give the appearance that a conflict of interest exists, even though they believe there may not be an actual conflict of interest. Thus, for example, a member should not participate in the deliberations and actions on any application from a recent student, a recent teacher, or a close personal friend. Judgment must be applied on the question of recency, frequency and strength of the working relationship between the member and the principal investigator as reflected, for example, in publications. Another example might be an application from a scientist with whom the member has had longstanding differences which could reasonably be viewed as affecting the member's objectivity.

At the end of the study section meeting, the Grants Assistant obtains written certification from all members that they have not participated in any reviews of applications from an organization where they are an employee, consultant, officer, director or trustee, or have a financial interest. In addition, each study section keeps a log, prepared by the Grants Assistant and maintained in the study section office, of which members left the room for conflicts and for what applications. This record is filed with the minutes from the meeting in the study section office.

a. Review of Applications from Multicampus Organizations and Multiple State-Supported Systems. Members must leave the meeting room when applications involving their own organizations are being discussed.

Where there are multiple state-supported higher education systems, for example the University of Florida and Florida State University, the terms "own organization" and "entire system" include all the state supported higher education systems.

However, higher educational systems within 22 states are considered separate entities sufficiently distinct from each other that no conflict-of-interest exists that would preclude a peer review group member from one entity from reviewing applications from another entity. Two examples are: (1) Colorado State University and the University of Colorado, and (2) the campuses of the University of California, the California State Universities and Colleges, and the California Community Colleges. The complete list can be found in the Handbook for Executive Secretaries. Chapter XII, Section A.2.a. Decisions pertaining to additional states may be made in the future on a case-by-case basis. (Current listings are available from the CMO)

State systems other than higher education systems, such as the state bureau of health or elements of the state hospital system, are separate entities not in a conflict-of-interest situation with each other or with the state higher education system.

b. Review of Applications Submitted by Colleagues-Associates. In addition, members should be urged to avoid any actions that might give the appearance that a conflict of interest exists, whether or not in any particular case the member believes there to be an actual conflict of interest. Thus, for example, a member should not participate in the deliberations and actions on any application from a recent student, a recent teacher, or a close personal friend. Another example might be an application from a scientist with whom the member has had longstanding differences which could reasonably be viewed as affecting the member's objectivity.

It is often difficult to decide whether or not an appearance of conflict of interest exists that is sufficient to warrant disqualification. Members should be told that if a situation arises about which a member has a question, the member should raise the matter in advance with the Executive Secretary.

c. NIH Staff Conflicts. Institute staff may not participate as members of study sections in the review of projects or applications if they have been, or are expected to be, involved in decisions or actions in the award or administration of the corresponding grants. Extramural Institute staff may attend study section meetings to provide administrative and program information necessary for the adequate review and evaluation of applications. They may not, however, join in the scientific-technical evaluations and recommendations of the study sections concerning these projects.

B. CONFIDENTIALITY

Review materials and proceedings of review meetings are privileged communications prepared for use only by consultants and staff. Reviewers are requested to leave all review materials with the Executive Secretary or Grants Assistant at the conclusion of the site visit or review meeting.

C. PRIVACY ACT

The Privacy Act of 1974 (Public Law 93-579) is designed to safeguard individuals from invasions of personal privacy by Federal agencies. This legislation permits individuals named in Federal records to:

- Determine what records pertaining to them are maintained by and used in a Federal agency;
- Prevent their records from being used for any purpose other than the intended one(s) without their permission;
- Gain access to their records; and
- Ascertain that the information concerning them is accurate.

Federal agencies must collect, maintain, or use the records of identifiable persons in a lawful manner, ensure that the records are accurate, and provide safeguards to prevent misuse. If provisions of the Privacy Act are violated, Federal employees can be subject to fines up to \$5,000.

The term "record" refers to any item of information, including handwritten notes, about an individual which can be traced to him or her by name, symbol, etc. The records that most concern the study section are those associated with the grant application review process, such as reviewers' written comments, project site visit reports, outside opinions, and summary statements. Reviewers' rough notes are not considered part of the record unless they have been transmitted to the NIH staff. Study section files are considered only part of the Institute official files, and therefore, any release of information must not be done by study section staff but by Institute staff.

The following materials should not be retained in the study section files:

- Outside opinions,
- Preliminary written comments by reviewers,
- Assignment lists,
- Scoring sheets,
- Check sheets that contain reviewers' names, and
- Project site visit reports, especially if they contain individual comments.

To implement the Privacy Act provisions, the NIH has set up the following system, with some variation among Institutes. Each Institute has a Privacy Act Coordinator who provides policy guidance to staff. Privacy Act Coordinators in some Institutes oversee systems of records in order to maintain their accuracy, amend the records if necessary, respond to Privacy Act requests, and review information to be released. In some cases, an access official is also involved in obtaining records and transmitting them to requestors. The list of the Privacy Act Coordinator for each Institute is found in the yellow pages of the NIH Telephone Book. The Privacy Act and Freedom of Information Act Officer for DRG is Dr. Joseloff, Chief, Office of Grants Inquiries. These Coordinators may contact an Executive Secretary to obtain needed information. In such an instance, the NIH position is that if the requested material is currently available, it must be released.

All written requests for information or records covered by the Privacy Act should be referred to the appropriate Institute Privacy Act Coordinator. A postcard or letter indicating that the request was forwarded and giving the name and address of the Coordinator should be sent promptly to the investigator by the study section office (Figure 79). This is helpful if the request is lost or the response delayed. The Institute must respond to the request within 10 working days of its receipt date.

The originals of all other incoming and copies of outgoing correspondence related to the Privacy Act are to be forwarded to the appropriate Institute. This includes letters from consultants who decline service on the study section because of the Privacy Act. An Executive Secretary or Grants Assistant should transmit to the assigned Institute any correspondence with persons other than study section members and NIH staff (for example, nonmember project site visitors) to whom an application was shown, as well as the names of persons from whom outside opinions were requested. In this connection, both study section members and outside referees must be informed of the Privacy Act regulations.

Although summary statements are sent to investigators by the Institutes as soon as possible after study section meetings, investigators may request summary statements. The Executive Secretary should refer these requests to the Privacy Act Coordinator of the Institute to which the application is assigned. If the request comes by mail, a postcard or letter indicating that the request was forwarded and giving the name of the Privacy Act Coordinator should be sent to the investigator.

D. FREEDOM OF INFORMATION ACT

The Freedom of Information Act of 1974 (Public Law 90-23), which is designed to allow public access to records held by Federal agencies, differs from the Privacy Act in that requestors are seeking records other than their own. Records requested under the Freedom of Information Act must be disclosed unless the records fall within one of nine areas of exemption. The three exemptions most relevant to the NIH are as follows:

- Trade secrets, commercial and financial information;
- Inter- or intra-agency memoranda or letters that would be available by law only by litigation with the agency; and
- Personnel or medical files whose release would constitute an invasion of privacy.

Each Institute has a Freedom of Information Coordinator, who is listed in the yellow pages of the NIH Telephone Book. Requests for information should be forwarded to the appropriate Coordinator. In some Institutes, the Freedom of Information and Privacy Act Coordinator are the same person. Written requests for information can be denied only by the Freedom of Information Officer, DHHS.

E. INVOLVEMENT OF HUMAN SUBJECTS

According to DHHS policy, the institution that receives awarded funds has primary responsibility for safeguarding the rights and welfare of human subjects-at-risk who participate in activities supported under grants and contracts from the DHHS. Every principal investigator must include, as part of the application, certification that if the application involves human subjects in research and is not in an exempt category, the application has been reviewed and approved for compliance with DHHS regulations by an institutional review board.

Notwithstanding any prior review, approval, or certification by the institution, all applications and proposals involving human subjects that are submitted to the DHHS must be evaluated by the staff and other experts or consultants for compliance with DHHS regulations. At the NIH, this evaluation is accomplished by IRGs, Councils, and NIH staff. The overall responsibility and authority for implementing the policies rest with the Office for the Protection from Research Risks (OPRR).

The regulations define "human subject" as a "living individual about whom an investigator obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." The regulations extend to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable state and local laws and is not directly regulated by 45CFR 46. The regulations also specify additional protections for certain classes of human research

involving fetuses, children to age 18, pregnant women, in vitro fertilization, mentally retarded, mentally disabled, and prisoners.

Exempt from coverage by the regulations are activities in which the only involvement of human subjects will be in one or more of the following six categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, and classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
3. Research involving survey or interview procedures, except where all of the following conditions exist: (i) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; (ii) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.
4. Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist: (i) observations are recorded in such a manner that the human can be identified, directly or through identifiers linked to the subjects, (ii) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.
5. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
6. Unless specifically required by statute, research and demonstration projects which are conducted by or subject to the approval of the DHHS, and which are designed to study, evaluate,

or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. However, if, following review of proposed research activities that are exempt from these regulations under this paragraph, the Secretary determines that a research or demonstration project presents a danger to the physical, mental, or emotional well-being of a participant or subject of the research or demonstration project, then Federal funds may not be expended for such a project without the written informed consent of each participant or subject.

The Executive Secretary must determine whether claims for exemption are appropriate. Applicants should include sufficient information in the research plan for the Executive Secretary to make the determination. If an exemption is claimed, a paragraph should be written under Section E explaining how the exemption applies to the research. If the proposed research does not appear to meet the requirements for exemption, the Executive Secretary should request appropriate certification from the applicant. This certification can be a new application face page with the proper signatures, a letter with the proper signatures, or Form HHS 596. It must be received no later than 60 days after the receipt deadline or three weeks prior to the study section meeting, whichever comes first. Lack of compliance requires deferral of the application.

It is important to determine if separate certifications are also required from institutions cooperating with the applicant organization. The two determinants are: (1) the cooperating institution's role in the project and (2) the "administrative control" of the applicant institution. If the cooperating institutions do not have an active role or if there is "administrative control" (i.e., an implicit acceptance of the applicant institution IRB review), then no separate certification need be submitted.

The study section evaluation of applications involving human subjects should take into account, among other pertinent factors, whether the subject is at risk, the apparent risks to the subject, the adequacy of protection against these risks, the potential benefits of the activity to the subject and to others, the importance of the knowledge to be gained, and whether informed consent will be obtained by adequate and appropriate methods. The six (6) points in Section E must be addressed if human subjects are involved.

Any concerns by study section members for the adequacy of the protection or welfare of human subjects or comments (suggestions) are indicated as a special note on the summary statement (Chapter X). This paragraph should fully list the reviewers' concerns or comments on the adequacy of protection of human subjects with explanations, and indicate whether there was a unanimous consensus on the concerns. Also, human subjects concerns or comments are indicated on the summary sheet by the human subjects code. No award will be made

until all expressed concerns about human subjects have been resolved to the satisfaction of the NIH.

F. ANIMAL WELFARE

The applicant institution and investigator bear the responsibility for proper care and use of animals. NIH staff, study sections, and Councils must be certain that applicants observe the rules and practices of good animal care as expounded in the NIH Guide for Grants and Contracts, Vol. 14, No. 8, June 25, 1985 and Guide for the Care of and Use of Laboratory Animals, NIH Publication No. 85-23 (Revised 1985). Care and use of vertebrate animals in funded projects must conform to applicable law and PHS policy, especially the Principles for Use of Animals. The general intent of these principles apply before, during, and after experimentation and can be summarized as two broad rules:

- The project should be worthwhile and justified on the basis of anticipated results for the good of society and the contribution to knowledge; and the work should be planned and performed by qualified scientists.
- Animals should be confined, restrained, transported, cared for, and used in experimental procedures in a manner to avoid any unnecessary discomfort, pain or injury.

Special attention should be given when the proposed research involves dogs, cats, nonhuman primates, large numbers of animals, or animals that are in short supply or are costly.

Institutions are required to establish a formal mechanism, including an institutional animal care and use committee (IACUC), to evaluate and monitor their animal care programs. A certification of committee review and institutional assurance are also required for applications involving vertebrate animals, and the points in Section F addressed.

No award will be made by PHS unless the responsible designated institutional official has verified that the care and use of animals in the proposed research has received the required IACUC review and approval. Verification of IACUC approval must be contained in the grant application or contract proposals, or be provided through a new application face page or a letter of verification within 60 days of submission if the institution has an approved assurance.

The Executive Secretary must document the study section's assessment of animal involvement by designating the correct animal subjects code using the DRG Interface System. As with human subjects, the chairperson must obtain a consensus for either a concern or comment (suggestion) so as to provide clear instructions for animal subject coding.

Additional details can be found in Manual Issuance 4206 and 6000-3-4.58: Responsibility for Care and Use of Animals.

G. HAZARDOUS RESEARCH MATERIALS AND METHODS

The investigator and the sponsoring institution are responsible for protecting the environment and research personnel from hazardous conditions. As with research involving human subjects, reviewers are expected to apply the collective standards of the professions represented within the study section in identifying any potential biohazards, for example inappropriate handling of biohazardous materials, such as oncogenic viruses, chemical carcinogens, infectious agents, recombinant DNA, and radioactive or explosive materials.

If applications pose special hazards, the Executive Secretary should identify the potential or actual hazards in the summary statement under the heading "Biohazard," and, if appropriate, suggest how the investigator might avoid or deal with the problem. To bring the concern to the attention of the NIH staff, the word "Biohazard" should be inserted above the word RESUME in the summary statement.

No award will be made until all concerns about hazardous conditions have been resolved to the satisfaction of the NIH.



National Institutes of Health
Bethesda, Maryland 20892
Building
Room
(301) 496-

(Date)

Re:

Dr.

Dear Dr. :

Your request to this office for material releasable under the Privacy Act has today been forwarded to the appropriate Institute/Division Privacy Act Coordinator listed below. You should hear from that individual at an early date.

Sincerely yours,

_____, Ph.D.
Executive Secretary
_____, Study Section
Division of Research Grants

FORWARDED TO: _____, National _____ Institute, NIH,
Building __, Room _____, Bethesda, Maryland -20892

GENERAL OFFICE MANAGEMENT

A. COOPERATION

Since each study section office is a small, self-contained unit, it is essential for the Executive Secretary, Grants Assistant, and Grants Clerk to have a good working relationship. Cooperation and mutual respect are necessary for a smooth running office. The Executive Secretary and Grants Assistant should keep each other informed about any absences from the office, whether for annual leave, illness, dental and medical appointments, or meetings. If an emergency arises, the Grants Assistant should notify the office or Lead Grants Assistant as early in the morning as possible so that contingency plans can be made.

B. TELEPHONE CALLS

The Grants Assistant will receive telephone inquiries or requests from study section members, Institute staff, and the public. These calls should be handled promptly and courteously. If calls are received from the offices of Congressmen or Senators concerning applications or study section business, form PHS 1553 (Figure 80) must be filled out and given to the Office of the Executive Officer, DRG (Room 452, Westwood Bldg.).

While information about study section actions may be provided to Institute and DRG staff, such information must not be released to anyone who is not entitled to it for official purposes. Any time after the study section meeting, investigators may inquire, frequently by telephone, about the action taken on their applications. Do not reveal the recommendation or priority score, but indicate that the request should be made in writing to the Privacy Act Coordinator at the appropriate Institute. The List of Coordinators is found in the yellow pages of the NIH Telephone Book.

If Institute extramural staff members inquire about study section actions before the summary statements have been written or typed, this information may be supplied. Occasionally, Grants Assistants are asked about the membership of the study section. Such information is not confidential as it is available in NIH Public Advisory Groups. However, information regarding the assignees on specific applications should never be divulged.

C. ATTENDANCE

Time sheets are filled out in duplicate for each study section office (Figure 81). The time sheet is taken to one's Lead Grants Assistant Friday morning before 11 a.m. Each person is responsible for recording his or her own leave on the time sheet, which is a record of all time worked and leave taken. If overtime during a weekend is involved, the completed original is due Monday morning. The original is an accurate record of all time worked and leave taken for the previous week.

All leave must be signed for on Form SF-71 (Figure 82). Sick leave should be signed for immediately upon one's return to the office; annual leave, except for emergencies, should be signed for in advance. Approval (the signature on the bottom of the form) is not always required. However, for more than 3 days of annual leave, Form SF-71 must be approved by one's supervisor. For more than 3 consecutive days of sick leave, Form SF-71 must be signed by the doctor or accompanied by a doctor's note. Problems in connection with time, leave, or payroll should be discussed with the timekeeper.

1. Flexitime

The Referral and Review Branch participates in a flexitime program, in which employees request and supervisors approve a specific time schedule. The starting time ranges from 7:00 a.m. to 9:30 a.m., the closing time from 3:30 p.m. to 6:00 p.m.. Once approved, the employee's assigned time schedule remains in force, but may be modified at any time with the supervisor's approval. Figure 83 explains in detail DRG's flexitime procedures.

2. Overtime Authorization

All overtime must be requested and approved in advance. For approval of other than routine overtime, the Grants Assistant informs the Lead Grants Assistant well in advance of the pay period in which the work is to be performed (approximately 3 weeks before the meeting). Any overtime for Institutes must be approved by the supervisor and Section Chief and should be limited to 10 hours. For the study section meeting, Grants Assistants are automatically put in by the Lead Grants Assistant for 2 hours of overtime - 1 hour to set-up and 1 at the end of the meeting if it runs after 5:00 p.m. Any overtime in excess of 2 hours must be requested on NIH Form 1962 (Figure 84).

3. Religious Comptime

All religious comptime must be requested in writing and approved in advance by the Deputy Chief for Review. Religious comptime can be earned up to 6 months before leave has been taken.

4. Executive Secretary Comptime

Comptime must be requested and receive prior approval by the Section Chief on NIH Form 1962.

D. STUDY SECTION FILES

The principal rules for filing should be

KEEP IT SIMPLE!

DON'T PACK-RAT!

KEEP CURRENT

1. Overall Guidelines

Some study sections find a unified filing system most convenient. All file folders are filed alphabetically by Institutes and then numerically within each Institute. This arrangement makes it simple to locate any file, even when only the number is known. With this system, however, it is absolutely necessary to have an efficient method for clearing the files of inactive material at regular intervals.

Other study sections have their files divided into two basic categories--active and inactive. With this system, the files for grants or approved applications may be returned to the active files after the study section meeting and before the Institutes have taken action on the current recommendations. Disapproved applications and terminated grants are placed in inactive files. Any deferred application is placed immediately with other materials for the upcoming study section meeting.

- a. Study Section Files. As described in Chapter V, the file usually contains materials that can be fastened on backers, with the most recent information on top. One copy of any additional information submitted by the applicant should also be included. In addition, a record of persons other than study section members who had access to the application for review purposes should be kept in the file. Even if an outside opinion request was not answered or was refused, or if a scheduled project site visitor did not attend the visit, that person's name should still be documented in the file. This file should contain not more than 3 copies of the most recent application and about 20 copies of the coordinating summary statement. (See Chapter V.) All copies of deferred applications should be kept so as to reduce the number of copies that must be reordered for the next study section meeting. The latest funded application and its corresponding summary statement should be kept in the main file.
- b. Reference Files. In addition to the file folders on each application, study sections find some type of quick reference file essential. Some study sections use looseleaf binders of summary statements filed alphabetically by the name of the principal investigator and numerically by Institute. These are easy to maintain. After each study section meeting, when summary statements

are collated for the minutes, a set can immediately be filed in each of these binders. When files are destroyed, this action can be recorded on the summary statements in the binders. These binders are kept for 10 years.

Other study sections use cards or roladex files. Filed alphabetically by name of the principal investigator, these cards are easy to use and do not take up much space. In addition to this, an alphabetical and/or numerical looseleaf binder must be kept for summary statements. When files are destroyed, this action is recorded on the roladex files. A record should be kept of any Request for Assignment Change (Chapter V) on applications that have been transferred or withdrawn before or immediately after the review. This is essential when trying to locate an application whose action has not been recorded on the computer.

Meeting files of complete summary statements do not need to be kept for more than 3 years after the review date. All that is necessary for reviewers dating back more than 3 years is a record of the application reviewed (application number, principal investigator, and title of application).

- c. Administrative Files. Each study section will have miscellaneous files containing information regarding meetings, study section members, general correspondence, and travel records. Also, each study section maintains a daily board containing a copy of every letter sent out from the office. Items on this board may be destroyed after a year and a half.

Disposal of Files

When cleaning out files, Grants Assistants should save and reuse file folders. Because the official NIH files with original materials are maintained in Institutes and the study sections have only "working files," it is not necessary to store materials in the study section office beyond the period when a grant is active or follow-up is expected. (Usually no further action can be expected after a grant has been inactive for 1 year.) Unless special reasons exist, there is no need to retain copies of appendices, progress reports, reprints, or manuscripts after the initial review of the application.

When a grant is terminated or when an application is withdrawn, disapproved, or administratively inactivated, the folder should be placed in the inactive category and retained for 1 year.

3. Material Not Kept in Files After Review

- Outside opinions
- Reference letters (RCDA's, Fellowships, FIRST awards)
- Preliminary written comments
- Checksheets containing reviewers' names
- Project site visit reports
- Reprints, manuscripts, and appendices

E. SUPPLIES AND EQUIPMENT

1. Self-Service Store

Requests for office supplies must be made on a requisition form (Figure 85) and submitted to the Lead Grants Assistant. The approved and signed form is then forwarded to the Office Services Section. The Grants Assistant will be called by a representative from Office Services to pick up the supplies at the Self-Service Store (Room 51, Basement, Westwood Building).

The store is open on Tuesday and Thursdays. Since office space is limited, it is recommended that as small a stock as necessary be kept in each office. Purchases should be made as needed.

2. Office Services Section, Administrative Branch, DRG

Furniture, name plates, and other special equipment, such as rubber stamps, are ordered by memorandum from the Office Services Section. Requests for repairs of equipment and any changes of offices are also handled through the Office Services Section. When typewriter repairs are requested, the typewriter make and serial number as well as a description of the difficulty should be supplied.

F. DRG CONTACTS

1. Civil Service Problems

Problems regarding grades, promotions, and training possibilities should be discussed first with the Lead Grant Assistant, and then, if necessary, with the Personnel Officer, DRG.

2. Employee Advisory Committee

The Employee Advisory Committee (EAC) is an Equal Employment Opportunity Committee through which an employee can be heard and helped. DRG employees are welcome to bring problems or suggestions directly to EAC representatives. Also the EAC has locked suggestion boxes located across from the elevator on the second, third and fourth floors and in Room 133 for criticisms, ideas, or general comments. Suggestions may be signed or submitted anonymously. The issues are then considered by the Committee and taken to the Director, DRG, for action.

3. Equal Employment Opportunity (EEO)

EEO problems should be discussed with an EEO representative. The DRG Officer is Ms. Emma Twyman.

4. Injuries or Accidents

Any mishap occurring in the office or on NIH property should be reported promptly to the resident nurse (Room 28, Westwood Bldg., 496-7638) and to the Lead Grants Assistant. Health Unit office hours are 8:30 a.m. to 5:00 p.m., Monday through Friday, except for Tuesday when the office closes at 2:40 p.m.

RECORD OF CONGRESSIONAL TELEPHONE INQUIRIES

PHS-1553
REV 3-63

CONGRESSIONAL INQUIRY RECEIVED AND ANSWERED BY TELEPHONE

| | | |
|-------------------------------------|------------------|--------------------|
| INQUIRY FOR OFFICE OF SENATOR | STATE | DATE |
| CALL RECEIVED FROM (Name and Phone) | CALL RECEIVED BY | BUREAU OR DIVISION |

INFORMATION REQUESTED AS FOLLOWS

THIS FORM MUST BE FILLED OUT AND GIVEN TO THE
OFFICE OF THE EXECUTIVE OFFICER, ANY TIME
ANYONE IN YOUR OFFICE RECEIVES A TELEPHONE
CALL FROM A CONGRESSMAN OR SENATOR'S OFFICE.

COPIES REQUIRED:

Original on form PHS 1553.

One white tissue copy.

Internal requirements.

FIGURE 81

| TIME SHEET Figure 74 | | | | Week Beginning <input checked="" type="checkbox"/> | | | | | | | | |
|---|------|------|--------------------------------------|---|-------------|------|--------------|------|------|-------|--------------|--------------|
| Sheets are due every Friday before 11.00 a.m. time, Comp must be authorized in advance. column is for Religious comp., Court leave, military leave, etc. | | | | Section or Unit <input checked="" type="checkbox"/> | | | | | | | | |
| | | | | Signature of Supervisor | | | | | | | | |
| NAME | DATE | DAY | IN | OUT | LEAVE TAKEN | | | | | | | |
| | | | | | ANNUAL | SICK | COMP EARN | LWOP | AWOL | OTHER | OVER TIME | COMP USED |
| ✓ | -- | SUN | | | | | | | | | | |
| | 7-4 | MON | Holiday | | | | | | | | | |
| | 7-5 | TUES | 8:30 | 5:00 | | | | | | | | |
| | 7-6 | WED | 7:30 | 7:00 | | | 3cc | | | | | |
| | 7-7 | THUR | 8:30 | 6:30 | | | 1 1/2 | | | | | |
| 30-5:00 | 7-8 | FRI | 8:30 | 3:30 | | | | | | | 1 1/2 | |
| | | SAT | | | | | | | | | | |
| 2 = religious comp | | | | | | | | | | | | |
| | | MON | | | | | | | | | | |
| | | TUES | Time in/out = when earning religious | | | | | | | | | |
| | | WED | comp, sign the <u>exact</u> | | | | | | | | | |
| | | THUR | hours worked. | | | | | | | | | |
| | | FRI | | | | | | | | | | |
| | | SAT | | | | | | | | | | |
| | | SUN | | | | | | | | | | |
| | | MON | | | | | | | | | | |
| | | TUES | | | | | | | | | | |
| | | WED | | | | | | | | | | |
| | | THUR | | | | | | | | | | |
| | | FRI | | | | | | | | | | |
| | | SAT | | | | | | | | | | |
| | | SUN | | | | | | | | | | |
| | | MON | | | | | | | | | | |
| | | TUES | | | | | | | | | | |
| | | WED | | | | | | | | | | |
| | | THUR | | | | | | | | | | |
| | | FRI | | | | | | | | | | |
| | | SAT | | | | | | | | | | |

SP 71
(Revised 3/79)
OFFICE OF PERSONNEL MANAGEMENT
PMA Sample PPO-2, S 2-9

71-112

APPLICATION FOR LEAVE

INSTRUCTIONS: Please complete items 1-8 after reading the Privacy Act Statement shown below.

| | | | | | |
|--|--|------------|-----|-------------------------|-------------------------------|
| 1. Name (Print or type—Last, First, M.I.) | | | | 2. Employee I.D. Number | |
| 3. Organizational Unit | | 4-A Month | Day | Hour | A.M. |
| | | FROM | | | P.M. |
| 5. I hereby request (If more than one box is checked, explain in Item 6, Remarks) | | 4-B Month | Day | Hour | A.M. |
| <input type="checkbox"/> Annual Leave. (Annual leave requested may not exceed the amount available for use during the leave year.) | | TO | | | P.M. |
| <input type="checkbox"/> Sick Leave. (Complete reverse side of form.) | | 6. Remarks | | | |
| <input type="checkbox"/> Leave Without Pay. | | | | | |
| <input type="checkbox"/> Compensatory Time. | | | | | |
| <input type="checkbox"/> Other. (Specify) | | | | | |
| 7. Employee's Signature | | | | | 8. Date (Month, Day, Year) |

OFFICIAL ACTION ON APPLICATION

| | | | |
|-----------------------------------|---|---|----------------------------|
| <input type="checkbox"/> Approved | <input type="checkbox"/> Disapproved (If disapproved, give reason. If annual leave, initiate action to reschedule.) | Signature: Annual leave approval may not exceed the amount available for use during the leave year. | Date (Month, Day, Year) |
|-----------------------------------|---|---|----------------------------|

PREVIOUS EDITION USABLE

NSN 7540-00-733-8067

EMPLOYEE—Check the appropriate box below (Items 1-4) if you are applying for sick leave. If your agency requires such certification, please have your doctor or practitioner complete the Certification section below. Falsification of information in this portion of the form may be grounds for disciplinary action, including dismissal.

| | | | |
|---|---|--|--|
| 1. I was incapacitated for duty by: | | 2. I was required to care for a member of my family with a contagious disease. (Give name and relationship of family member, and name of disease.) | |
| <input type="checkbox"/> Sickness. | <input type="checkbox"/> Off-The-Job Injury. | <input type="checkbox"/> | |
| <input type="checkbox"/> On-The-Job Injury. | <input type="checkbox"/> Pregnancy and Confinement. | | |
| 3. I was undergoing medical, dental, or optical examination or treatment. | | 4. I was exposed to a contagious disease. (Give name of disease and circumstances of exposure.) | |
| <input type="checkbox"/> | | <input type="checkbox"/> | |

CERTIFICATION OF PHYSICIAN OR PRACTITIONER

| | | |
|-----------------|--|----|
| Employee's Name | Period Under Professional Care (Indicate Month, Day, Year) | |
| | From | To |
| Remarks | | |

I certify that the employee named was under my professional care for the period indicated above, and that the employee's condition during this period made reporting to work inadvisable.

| | |
|--|-------------------------|
| Signature of Physician or Practitioner | Date (Month, Day, Year) |
|--|-------------------------|

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

October 1, 1987

Director, DRG

Flexitime in DRG

All DRG Staff

I am pleased to report that, effective with the pay period beginning on October 11, 1987, the Division of Research Grants will institute a new form of Flexitime known as Modified Flexitour. For your convenience, the guidelines that apply are attached to this memorandum.

Under the Modified Flexitour system, both the employee and the supervisor have new opportunities, flexibilities, and responsibilities. It is important that all of us understand and carefully observe the rules so that we do not jeopardize these new benefits. As you will see when you read the attached guidelines, it is now possible to adjust your starting time and ending time if your supervisor concurs. Also, if you first obtain your supervisor's permission, you may change your starting time to accommodate unavoidable circumstances such as taking your car to the shop or seeing your doctor or dentist.

Another advantage of the new Modified Flexitour system is that your supervisor may, at his or her discretion, excuse tardiness of up to 30 minutes in unusual or emergency situations. Any such excused tardiness requires that the employee will work the "missed" minutes at the end of the day.

For a while the Modified Flexitour system will be new and different for some of us, so do not hesitate to ask questions. Information can be obtained from our Personnel Office staff (Room 434; X7577) or from Pat Bailey or Jean Gunton (Room 454; X7881). To assist you in further understanding this new system, we have attached a list of frequently asked questions, along with the proper answers.

Jerome G. Green, M.D.

Attachments

DRG FLEXTIME PROGRAM

Official Hours: 8:30 a.m. to 5:00 p.m., Monday through Friday.

Basic Workweek: All full-time employees are required to work a basic eight-hour day in a work tour that includes, in addition to the eight hours, a 1/2 hour lunch period. The basic workweek, therefore, consists of five days, Monday through Friday, totaling 40 hours.

- Employees are authorized to take the standard lunch period, between 11:30 a.m. and 1:30 p.m.
- Employees may not work through lunch and leave at the end of eight hours. Under the Flexitime concept, the prescribed hours of duty are considered eight hours from the time the employee "signs in", excluding a mandatory 30-minute lunch period.

Flexitime Hours:

| Flexible Band | Core Time (includes lunch) | Flexible Band |
|------------------|-------------------------------|------------------|
| 7:00 - 9:30 A.M. | 9:30 A.M. - 3:30 P.M. | 3:30 - 6:00 P.M. |

- The morning flexible band of time is from 7:00 a.m. to 9:30 a.m.; core time is from 9:30 a.m. to 3:30 p.m. (including lunch); and the afternoon flexible band of time is from 3:30 p.m. to 6:00 p.m. Subject to the needs of the office, as determined by the supervisor, each employee will select a fixed starting time between 7:00 a.m. and 9:30 a.m. The workday will end at any time between 3:30 and 6:00 p.m. as long as the employee has worked or otherwise accounted for eight hours each day plus the lunch period.
- A degree of flexibility on either side of the approved starting time is permitted up to 30 minutes. For example, if a schedule of 7:30 a.m. is approved, the employee might be permitted a 30-minute variation on either side of 7:30. Therefore, if the employee begins as early as 7:00 a.m., that becomes the employee's starting time for that day and that one half-hour counts toward the completion of the 8-hour day. By taking no time off other than the normal lunch break, the employee's day would end at 3:30 p.m. Conversely, an employee arriving later than 7:30 a.m. but not later than 8:00 a.m.

begins the day at that time and is not considered tardy. By taking no time off other than the normal lunch break, the employee's day may end as late as 4:30 p.m.

- An employee may request an occasional change in starting time to accommodate personal needs. Approval of the supervisor must be requested one day in advance except in an emergency.
- Deviations from the flexitime schedule may be required by management due to workload. It is recognized that office coverage must be maintained between 8:30 a.m. and 5:00 p.m. When necessary, the supervisor may assign employees to work hours to cover these needs on a fair and equitable basis.
- To the extent feasible, meetings will be scheduled during core hours. When this is not possible, meetings should be scheduled between 8:30 a.m. and 5:00 p.m.

Time Accounting: Employees must record all arrivals and departures except for the standard lunch break.

- The time on the sign-in sheet would be the time the person actually signs his/her name as entering on duty or leaving duty status. The same clock should be used to record time for all employees at a particular sign-in point.
- The following actions constitute falsification of official records and may be the basis for disciplinary action:
 1. An employee signing-in or out for another employee, except as authorized by the Executive Officer, DRG.
 2. An employee signing-in and recording an earlier arrival or leaving early and recording a later sign-out time; and
 3. An employee signing in and then leaving the office on other than official business.
- The completed sign-in sheets must be kept on file for a period of two years along with other employee time records.

Leave: Flexitime does not change an employee's right to annual or sick leave. The supervisor retains the authority to approve in advance requests to use leave.

Hazardous Weather: For delayed openings, the NIH official operating hours, 8:30 a.m. to 5:00 p.m. will be in effect. For example, if opening is delayed two hours, nonessential employees report to work at 10:30 a.m. and leave at 5:00 p.m. Delayed openings are rare. More

typically, a liberal leave policy would be in effect (leave is authorized without prior supervisory approval) and the employee would follow his/her regular schedule.

Training: Employees who are scheduled to attend training sessions may be required to readjust their scheduled hours or to revert to the NIH official operating hours during the training period.

WHAT EMPLOYEES ALWAYS WANT TO KNOW ABOUT FLEXTIME
AND ARE NEVER AFRAID TO ASK

- Q: My carpool got caught in traffic and I was 30 minutes late. Do I have to take leave?
- A: Not necessarily. A supervisor has discretion in this area. If the employee's excuse is acceptable, the supervisor may grant administrative leave for a brief tardiness. Otherwise, the employee may be allowed to work an equal amount of time at the end of the day, or be charged annual leave, leave without pay, or absent without leave as appropriate.
- Q: Can a supervisor grant administrative leave in conjunction with lunch?
- A: Yes. The reason for the absence (Traffic, retirement luncheon etc.) must be adequate and acceptable to the supervisor.
- Q: Some supervisors deny flexible work hours only because they work 8:30 a.m. to 5:00 p.m. and there is no supervisor available at other times. Is this permissible?
- A: The supervisor in that case is encouraged to explore other systems to allow the employees supervised to work flexible hours. It is suggested that in the absence of the regular supervisor, consideration be given to an officer-in-charge concept where responsible senior officials would be designated to serve as supervisors; or a rotating list be established of individuals whose working hours would be coordinated to assure that at least one person would be on duty at all times to exercise supervisory responsibility. If no reasonable options are available, the supervisor may disallow a request for flexible work hours because of lack of supervisory coverage.
- Q: Does flexitime apply to part-time employees?
- A: Yes. The approval of flexitime would be based on the same principles as for full-time employees; i.e., the needs of the office.
- Q: There are three secretaries in this office who answer the phones. Two are allowed to work flexible hours while I am required to work 8:30 a.m. to 5:00 p.m. to provide telephone coverage. Is this permissible?

FIGURE 83 (cont)

- A: It is recognized that minimum coverage must be maintained between 8:30 a.m. and 5:00 p.m. When and where necessary, the supervisor may assign employees to work hours to cover these needs on a fair and equitable basis.
- Q: Does everyone in the office have to use the sign-in and sign-out sheets?
- A: Yes, all employees must sign in and sign out regardless of their tour of duty.

**REQUEST FOR AND AUTHORIZATION (OR APPROVAL)
OF OVERTIME WORK**

These employees will be required or were required to work overtime on the dates and for the number of hours shown below. An entry of OT after the number of hours indicates that the employee requested compensatory time in lieu of payment for overtime.

NOTE: Overtime must be authorized prior to its performance except in cases of emergency according to current regulations. Overtime actually worked under this authorization must be recorded on the Time and Attendance Report (HEW-402) for the current pay period, and a cross reference made on that form indicating overtime was approved.

| EMPLOYEE'S NAME AND ORGANIZATIONAL UNIT | OVERTIME AUTHORIZED | | PAYROLL TIME AND LEAVE CLERK | |
|--|---------------------|---|------------------------------|----------|
| | NO. OF HRS. EST. | DATE | PAY PERIOD NUMBER | INITIALS |
| | | (Indicate rc if requesting religious comp.) | | |
| | | | | |
| | | | | |
| ication: Dates and reason for working | | | | |
| vertime/ religious comp. time | | | | |
| | | | | |
| ve Secretary | | | | |
| | | | | |
| igious comp: list the dates of the | | | | |
| us holidays when the comptime will be used. | | | | |
| | | | | |
| | | | | |
| vertime/religious comptime must be approved by the Deputy Chief. | | | | |
| | | | | |
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| | | | | |
| | | | | |

Authority for approving payment for overtime or the allowance of compensatory time in lieu of payment for overtime may be granted only by the officials delegated this authority in HEW Personnel Manual, Chapter 250 and operating agency supplement thereto. The delegated official must sign each request for overtime.

| | | |
|---|--|-------------------|
| AUTHORIZING OFFICIAL _____ Date, 3-2-1972 | SIGNATURE OF AUTHORIZING OFFICIAL _____ | DATE _____ |
|---|--|-------------------|

REQUISITION FORM FOR OFFICE SUPPLIES
STOCK REQUISITION

CHECKED BY _____ NO PROB. _____

DO NOT TYPE BELOW THIS LINE

| | |
|------|--|
| Date | |
|------|--|

AVAILABLE RESOURCES

A. REFERENCE MATERIALS

The Committee Management Office (CMO), DRG, Room 453, Westwood Bldg., has American Men and Women of Science and the Who's Who in America. Current copies of the Official Airlines Guide, the Hotel and Motel Red Book, various maps, travel guides, and the Highway Mileage Guide to assist in developing travel plans for site visits, out-of-town study section meetings, workshops, and other scientific meetings can be found in Room 1A06.

B. PUBLICATIONS1. Directories, Rosters, Schedules

- Competency Rosters of NIH Initial Review Groups
Available in the Committee Management Office, DRG. Study Section offices are notified when these books are available.
- DHHS Telephone Directory
Includes PHS offices located in the Parklawn and other DHHS buildings. A copy for reference use is available from the Office of Section Chiefs (Room 340, Westwood Bldg.).
- National Zip Code Directory
Available in the Self-Service Store. A copy for reference use is in the Office of the Section Chiefs.
- NIH Public Advisory Groups - Authority, Structure, Functions, Members
Issued annually by and available in the Committee Management Office, DRG.
- NIH Telephone and Service Directory
Published once a year. Alphabetical as well as organizational listings. Yellow pages include information on services of general interest. Distribution is automatic to NIH offices.
- Schedule of Initial Review Group Meetings - Alphabetical and Chronological Listings
Can be ordered from IMPAC.
- Schedule of PHS National Advisory Council Meetings
Ordered from IMPAC.
- Listing of Study Sections and Referral Staff
Issued by the Office of the Associate Director for Referral and Review, DRG (Room 338, Westwood).

- Tentative Schedule of National Advisory Council and Committee Meeting - Fiscal Year
Issued annually by the DRG Office Services Section.

2. General Reference Books

- Correspondence Manual (DHEW)
Can be requested from the DRG Office Services Section (Room 436, Westwood).
- Government Printing Office Style Manual
Can be requested from the DRG Office Services Section.
- Gregg Reference Manual
Available in the Self-Service Store.
- Medical Dictionary
Available in the Self-Service Store.
- Reference Manual for Stenographers and Typists
Used in NIH training courses. Available in the Self-Service Store.
- Webster's New Collegiate Dictionary
Available in the Self-Service Store.
- Word Division
Available in the Self-Service Store.

3. Extramural Program Policy Guides and Handbooks

- Activity Codes, Organizational Codes and Definitions Used in Extramural Programs
Available from Data Processing Section, Statistics and Analysis Branch, DRG, and issued periodically to study section offices.
- Handbook for Executive Secretaries, DRG
Available in the Grants Inquiries Office, DRG. A copy should be kept in each study section office.
- Handbook for Grants Assistants, DRG
Available in the Grants Inquiries Office, DRG (Room 449, Westwood). A copy should be kept in each study section office.
- Instruction and Information (I&I) Memoranda
These memoranda on NIH policy and procedures are issued periodically by the Office of the Associate Director for Extramural Research and Training, NIH, the Office of the Director, NIH, or another NIH administrative office. I&I memoranda have stated expiration dates. Those memoranda pertinent to the extramural programs should be kept together

in a looseleaf binder. A complete set of I&I memorandum is available for reference use in the Office of the Executive Officer, DRG. To order a particular I&I Memoranda, order forms are available from the Grants Inquiries Office.

- NIH Guide for Grants and Contracts
The Guide, which announces scientific initiatives by Institutes and provides policy and administrative information to the scientific community, is available in the Grants Inquiries Office, DRG, and distributed to study section offices. To be placed on the mailing list for this publication, complete a form available in the Grants Inquiries Office.
- NIH Manual Issuances
Those policy and procedure issuances pertinent to the extramural programs should be kept in a looseleaf binder. A complete set of Manual Issuances is available for reference use in the Office of the Executive Officer, DRG, except for those issuances pertaining to procurement and travel. The latter are kept in the DRG Travel Office (Room 455A, Westwood Bldg.).
- NIH Travel Handbook
Revised periodically. Distributed by the DRG Administrative Office.
- Orientation Handbook for Members of Scientific Review Groups
Available in the Committee Management Office, DRG.
- Proceedings of the Previous Meetings of the Chairpersons of NIH Scientific Review Groups
Available in the Office of the Associate Director for Referral and Review, DRG.
- PHS Grants Policy Statement
Available in the Grants Inquiries Office, DRG.
- PHS Manual Laws and Regulations
A complete set of these laws and regulations is available for reference use in the Office of the Executive Officer, DRG, Room 448.
- Research Awards Index
Vol. I. Index Section
Vol. II. Project Identification Data
Research Contracts
Alphabetical List of Investigators

Available in Research Documentation Section, Statistics and Analysis Branch, DRG (Room 148, Westwood).

4. Journals

The various scientific journals received by the Division are kept in the Journal Room, WB, Room 1A06.

C. Forms

Some general forms and guidelines used by all study sections are available from the open shelf files in the Third Floor Duplicating Room (Room 332, Westwood).

D. EQUIPMENT

Copying machines located on each floor. In addition, various office machines may be borrowed by study section offices through the Office Services Section.

E. SPEAKER PHONES

DRG has several speaker phones available for conference calls. To reserve a speaker phone call the respective offices:

Dr. Friedman - 496-7023;
Dr. Straat - 496-7447;
Dr. Ketley - 496-7558; or
Mr. Wassell - 496-7881.

For the one located in Conference Room 428, call Ms. Williams - 496-7211.

F. COMPUTER AIDS

Through the IBM Displaywriter and a modem, a Grants Assistant can access the NIH computer systems and independently retrieve valuable information or obtain useful services. The priority score computing system has been mentioned previously, but other capabilities also exist. Instructions can be found in the User Resource Office (496-1061).

INDEX

Academic Research Enhancement Award (R15-AREA) 13, 63, 67, 75, 135-136, 205

Activity Codes 55, 62-65

Ad Hoc Reviewers (see Special Reviewers)

Additional Information From Applicants 74, 126, 157, 161, 164

Administrative Branch, DRG 33, 255

Administrative Notes (Summary Sheets) 199

Agenda (Meeting) 35, 162, 164, 165-166, 173, 187

AHR Study Section Codes 12-13

Amended Applications 56, 78

Animal Welfare 73, 112, 113-114, 130, 132, 134, 136, 140, 147, 151, 158, 192-193, 201, 247

Appointment of Study Section Members 17, 28-30

Assignees 72, 78, 125, 129-140, 161, 162

Assignment List 125, 156, 163, 164, 180

Assistant Chiefs (See Section Chiefs)

Awarding Unit 55, 59, 66

Biohazards 130, 132, 134, 136, 140, 147, 151, 199, 248

Budgets 36, 74, 76, 78, 114, 129, 132-134, 136-137, 143-144, 146, 148, 162, 189, 192-193, 200

 Recommended 112, 192, 198

 Requested 129, 132, 134, 136, 146, 162

 Revised 78, 189

Chairperson 12, 17-18, 148-149, 165-166, 188, 223(SSS)

Chief, Referral and Review Branch 9, 233

Committee Management 11, 15-19, 23, 37, 126, 205, 263

Computer 15, 33, 57-59, 76, 125, 163-164, 192-193, 197, 202, 266

Conference Rooms 33-36, 39-41, 187

Confidentiality 144-145, 152, 188, 242

conflict of interest 12, 15, 73, 125-126, 145, 151-152, 154, 159, 160-161, 165,
 187-188, 206, 209, 221(SSS), 223, 239-242

Copy Machines 266

Correspondence 126-127, 233-234

Councils 2-3, 76-77, 80, 126, 165, 197, 233-235

Data Control Unit 59, 76-77

Deadlines 13

Referrals 73, 76, 80, 149, 198-199, 201-202, 253

Director, DRG 14-15, 17, 255

Distribution Chart 76, 78, 117-120, 205-206

Executive Secretary 3-4, 11-13, 15-18, 71-73, 78-79, 125-127, 165-166, 188,
 191-192, 211, 221-222, 233-234, 239-241, 246-247

Fellowship Applications 12, 62, 67-68, 73, 76, 139-140, 198, 202, 240, 254

Files, Filing Systems 73-74, 78, 80, 126, 226, 253-254

RST Award Applications 63, 75, 133-134, 254

Flexible Study Sections 12, 240

Foreign Applications 60, 130, 149-150, 199

Freedom of Information Act 244

Grant Application Kits 56, 67

Human Subjects 73, 84, 85-111, 114-116, 130, 132, 134, 136, 139, 146, 150-151,
 192-193, 201, 244-247

IBM Displaywriter 73, 191-193, 266

Institutes 1, 2, 5, 16, 18, 71, 75-79, 126-127, 161, 193, 197, 205, 221-222,
233-235, 242-243, 251, 253-254

Institute Representatives 18, 242

Interim Report 191

Interim Summary Sheet (Green Sheet), Project Site Visits 201

Field Grants Assistants 9-10, 197, 202, 205, 251, 255

Liaison Representatives 18

List 163

Meetings 78, 161-163

Mail Ballot, Meetings (Study Section) 224

Minutes 164, 205-207

Nominations (Study Section Members) 13-17, 23-27

Observers 18, 78, 162, 165

Office of Grant Inquiries 56, 164, 243, 264-265

Office Services 163, 166, 255, 264

Organization

HHS, NIH, DRG, RRB 1, 3, 5, 7-10

Out-of-Town Meetings, Workshops 34-36, 43-46, 166, 187, 189

Outside Opinions 72, 126-127, 160-162, 189, 199, 233, 254

Overtime 252, 260

PHS 398 Application Kit 56, 73-74

Print Shop 59, 69, 71-72, 193, 202, 225

Priority Scores 149, 191-192, 193, 200, 235, 266

Privacy Act 126, 130, 132, 134, 136-137, 140, 147, 160, 224, 227, 242-243, 249, 251

Processing of Applications 55-69, 71-80

Project Control 56-60, 71-72, 76-77, 81, 123

Project Site Visits 127, 162, 201, 211-212, 224-225(SSS), 234, 253-254

Receipt Dates for Applications 57, 68

Referral Section 2, 55-69, 71, 76-77, 79-80

Request for Assignment Change 58, 76-77, 80, 123, 254

Institute, Study Section, Institution 58-59, 76-77, 79-80, 121-122

Research Career Development Award Applications 62, 67, 75, 131-132, 198, 202, 254

Reservations

Hotel, Travel 33, 35, 212

Resume of Recommendations 192-193, 206, 208, 225

Resume of Transactions, (ROT) 58, 80

Review Procedures 148-153, 162, 164

Revised Applications 56, 78, 199

Reviewers' Guidelines 129-153, 162

Rosters 17, 19, 32, 35
 Scientific Review and Evaluation Award (Chairman's Grant) 12-13, 18, 24, 31, 36, 224-225(SSS)
 Scoring Sheets 163-164, 167, 177, 189, 191
 Seating Chart 164, 165, 181, 187
 Section Chiefs 9-10, 14-16, 18, 34-36, 197, 222-226(SSS), 252, 263
 Self-service store 163, 166, 198, 255, 263-264
 Small Business Innovation Research Applications 12-13, 63-64, 67-68, 75, 141-147, 205, 221
 Speaker Phones 266
 Special Notes on Summary Statements 199, 201-202, 246
 Special Reviewers 19
 Special Study Sections 12-13, 221-231
 Split Votes 149, 191, 199
 Status Reports 197, 203
 Study Section Office 78, 161, 166, 251-255
 Study Section Rosters 19, 162, 164, 166, 174-175, 187, 201, 205, 206, 223(SSS)
 Summary Statements 74-76, 79, 162, 192-193, 197-203, 224-226, 233, 253-254
 Supplemental Applications 56, 68, 198
 Telephone Conference Calls 35, 47, 224-225, 228, 231
 Telephones 33, 35, 187, 243-244, 251, 257, 263
 Transferred Applications 71, 76
 Transportation 166-167, 185, 212
 Travel 34, 48-49, 164-165, 182-184, 191, 211-220, 225-226(SSS), 229-230, 265
 Types of Applications 55, 59, 61
 User Resources Office 15, 33, 73, 125, 163, 166, 192, 199, 202, 225, 266
 Withdrawn Applications 58, 79, 80
 Workbooks 72, 78, 126, 161-162, 165, 187
 Workshops 18, 36-37, 41, 50-53
 Worksheets 125, 155, 164, 169, 179

